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Q. Is there a survey in the medical literature, something that says the percentage of pelvic floor surgeons who do the autologous pubovaginal sling and for those, you know, what percentage does it in a different manner?
A. I'm sure there is not.
Q. And I'll tell you why I'm asking. I deposed Dr. Rosenzweig the other day and he told me he makes like a 3 or -- he told me, literally, I think he said 2 to 4 centimeter, that's how big his fascial sling is.
Is that -- that's not how you do it, right?
A. Correct.
Q. Why would he --
MS. FITZPATRICK: Objection.
Q. So you don't know in the literature a breakdown by urologist, urogynecologists, people who are Board certified in the new certification, what percent of what specialty or subspecialty does a particular technique or approach for autologous sling?
MS. FITZPATRICK: Objection.
A. I don't --
MS. FITZPATRICK: Hypothetical --

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hypothetical calls for speculation, beyond the scope.
A. I don't. But I do have an opinion that the majority nowadays use a short sling for the reason that I just said. And the reason that I alluded to before is that because of the advertising -- in my judgment -- because of the advertising of all the mesh sling companies and the adoption by all of the societies of the concept and the validity of mesh slings, people that believed that mesh slings have -- that there is a reason to do autologous slings have adopted to a large extent the same flawed technology of the mesh slings and applied it to autologous slings. So it doesn't surprise me that the complication rate would be higher when they do that.
Q. But you don't know the percentage of surgeons who are doing this short or flawed technique, as you call it, right?
A. I do not.
Q. And you don't know in what percentage of the fellowship programs in this country that short or flawed technique for people of vaginal slings are taught, correct?

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A. Correct.
MS. FITZPATRICK: Objection.
Q. If at all, correct?
MS. FITZPATRICK: Objection.
A. Correct.
Q. Do you teach the full-length autologous sling at -- is it Columbia?
A. Cornell.
Q. Cornell, I'm sorry.
A. I do.
Q. Okay. Nobody -- does anybody else teach that short or flawed technique?
MS. FITZPATRICK: Objection.
We're done.
A. I don't know.
MS. FITZPATRICK: That's it.
Q. Fair enough.
MS. FITZPATRICK: You asked for three. You got 12 questions.
MR. SNELL: That's because his answers were leading me into other areas --
MS. FITZPATRICK: Well, you should have started down this road before.
MR. SNELL: -- of interest.

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(Time noted: 4:08 p.m.)

CERTIFICATE

I, SILVIA P. WAGE, a Notary Public for the State of New York, Certified New Jersey Court Reporter, Certified Realtime Reporter and Registered Professional Reporter, do hereby certify that prior to the commencement of the examination, JERRY G. BLAIVAS, M.D., was duly sworn by me to testify the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

_____

Notary Public of the State of New York
My Commission expires November 29, 2018
Dated: September 27, 2015

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 349, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
JERRY G. BLAIVAS, M.D., DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.

My commission expires:_____

_____
Notary Public

LAWYER'S NOTES

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Infect Dis Obstet Gynecol 2003;11:161–165

Bacterial colony counts during vaginal surgery

Patrick Culligan[1], Michael Heit[1], Linda Blackwell[1], Miles Murphy[1], Carol A. Graham[1] and James Snyder[2]

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Objective: To describe the bacterial types and colony counts present before and during vaginal surgery.

Methods: A descriptive study was undertaken of patients undergoing vaginal hysterectomy with or without reconstructive pelvic surgery. Aerobic and anaerobic bacterial cultures were obtained immediately before and throughout the surgical cases at preselected time intervals. Standard antimicrobial prophylaxis was administered in all cases. Mean total colony counts and mean anaerobic colony counts were determined by adding all colonies regardless of bacteria type. 'Contamination' was defined as ≥ 5000 colony-forming units/ml.

Results: A total of 31 patients aged 26 to 82 years (mean age ± SD, 51 ± 15) were included. The highest total and anaerobic colony counts were found at the first intraoperative time interval. On the first set of cultures (30 minutes after the surgical scrub), 52% (16/31) of the surgical fields were contaminated, and at 90 minutes, 41% (12/29) were contaminated. A negligible number of subsequent cultures were contaminated.

Conclusions: Any future interventions designed to minimize bacterial colony counts should focus on the first 30 to 90 minutes of surgery.

Key words: POSTOPERATIVE INFECTION; VAGINAL HYSTERECTOMY

Post-hysterectomy wound infections primarily result from the ascending spread of micro-organisms from the upper vagina[1]. Prior to the widespread use of prophylactic antibiotics, the rate of wound infection after vaginal hysterectomy was around 30–40%[2]. This unacceptably high infection rate prompted at least 25 randomized controlled trials and two meta-analyses[3,4], all of which supported the use of prophylactic antibiotics to decrease the infectious morbidity rate and length of hospital stay associated with vaginal hysterectomy. As a result, the American College of Obstetricians and Gynecologists currently recommends the use of antimicrobial prophylaxis for all patients undergoing vaginal hysterectomy[5]. The current rate of operative site infection after vaginal hysterectomy has declined to between 2.1% and 9.5%[6].

Nevertheless, infection remains the most common complication associated with vaginal hysterectomy[7]. Of the nearly 600 000 hysterectomies that are performed in the USA each year, about 150 000 (25%) are performed vaginally[8]. Using the above figures (i.e. multiplying the infection rate[6] by the number of vaginal hysterectomies[7]), the number of wound infections following vaginal hysterectomy in the USA may be estimated to be between 3150 and 14 250 per year.

An ideal strategy for continuing to lower infection rates after vaginal hysterectomy would be to conduct randomized controlled trials using

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operative site infection as the primary outcome measure. However, such studies would require large numbers of patients in order to detect a clinically significant difference in postoperative infections. For example, a randomized controlled trial with 80% power for detecting a reduction in infection rate from 6% to 3% would require 814 patients in each arm. Such a study would be very difficult and expensive to complete.

Use of a surrogate end point as the outcome measure might allow researchers to design more feasible studies. Bacterial colony counts in the vaginal field would be a reasonable surrogate end point for randomized controlled trials, because operative site infections following vaginal hysterectomy are thought to result from direct contamination by vaginal flora[7]. Any intervention that reduces the bacterial colony counts present in the operative field might therefore reduce operative site infection rates.

However, before this surrogate end point could be used in a randomized controlled trial, we need to know the baseline bacterial colony counts present throughout typical vaginal surgery. To date, this information has not been reported. Therefore, the objective of the present study was to describe the bacterial types and colony counts present before and during vaginal surgery. Our specific aim was to generate pilot data for a randomized controlled interventional trial with the goal of reducing bacterial colony counts present in the operative field during vaginal surgery.

MATERIALS AND METHODS

This was a descriptive study approved by the University of Louisville Health Sciences Center Human Studies Committee. Between September 2001 and April 2002, all patients undergoing vaginal hysterectomy with or without pelvic reconstructive surgery in our center were offered enrollment. No patients refused enrollment.

Standard infection prophylaxis, including preoperative intravenous antibiotics and a 5-minute surgical scrub with povidone–iodine, was used for all patients. Preoperative antibiotics were administered between 30 minutes and 2 hours prior to the start of each operation. Cefazolin (1 g) was used unless an allergy to this medication was reported. The alternative antibiotic regimen consisted of 900 mg of clindamycin and 120 mg of gentamicin.

Immediately prior to administration of the preoperative antibiotics, baseline aerobic and anaerobic cultures of vaginal flora were obtained. A standard technique was used to collect these cultures. All cultures for this study were obtained using a combined aerobic/anaerobic collection and transport system (CultureSwab™ Plus, Becton Dickenson, Franklin Lakes, NJ, USA). With the patient in the dorsal lithotomy position, a swab was placed in the posterior vaginal fornix and agitated throughout the length and circumference of the vagina in a standard fashion for 1 minute. Care was taken to include the entire surface area of the vagina, but the cervix was avoided. We chose not to obtain cultures via vaginal washings because of the inherent difficulty of retrieving fluid from the operative site during vaginal surgery.

A similar standardized technique was used to obtain cultures of the vaginal field 30 minutes after completion of the surgical scrub and hourly thereafter throughout each patient's surgery. Exact time intervals between cultures were determined with a stopwatch. When it was time for a given culture, the surgeon would swab the entire vaginal field, avoiding the cervix or peritoneal cavity.

Immediately after each operation, the culture transport tubes were taken to the University of Louisville Hospital Microbiology Laboratory for processing. All swabs submitted for culture were placed in 1 ml of sterile saline and vortexed. A sterile, calibrated (0.01 ml) loop was used to inoculate the specimen on to 5% sheep blood agar and chocolate agar plates which were incubated at 35°C in 5–10% carbon dioxide (aerobic cultures). Cultures for anaerobic microorganisms were inoculated quantitatively on brucella blood agar (BBA), phenylethyl alcohol agar (PEA), kanamycin vancomycin agar (KV), and *Bacteroides* bile esculin agar (BBE). Manual colony counts were reported for all positive cultures, with identification performed according to standard biochemical methods. The approach to quantifying microbial flora involved a 0.01-ml calibrated loop. Using this technique, one colony is equivalent to 100 colony-forming units/ml of specimen. A total

colony count was determined, and this was followed by observing and then counting each specific colony type. We do not routinely screen patients for bacterial vaginosis prior to vaginal surgery. None of the patients in this group were screened for bacterial vaginosis because none of them presented with clinical findings consistent with that disorder.

Our end point of interest was defined in two ways, each in relation to the timing of the various cultures taken before and during surgery. First, we defined our end point as a continuous variable by calculating the mean total and anaerobic colony counts at each designated time interval. Mean total colony counts were calculated by adding all colonies of bacteria found at a given time interval regardless of species, and then dividing by the number of patients in question at each time interval. Mean total anaerobic colony counts were determined at each time interval in a similar fashion.

Secondly, we defined our end point as a categorical variable by labeling the vaginal field 'contaminated' if total bacterial colony counts were ≥ 5000 colony-forming units/ml. This cut-off value for contamination was chosen because it correlates with a reading of 1-plus on simple dipstick analysis. We also followed the postoperative course of each patient in the study group to identify any operative site infections.

Descriptive statistical analysis for the group was performed using SPSS version 11.0 (SPSS Inc., Chicago, IL, USA). No group comparisons were performed because this was a simple pilot study.

RESULTS

A total of 31 patients ranging in age from 26 to 82 years (mean ± SD, 51 ± 15 years) were included. Operative times ranged from 25 to 270 minutes (average time, 156 ± 61 minutes). A total of 26 patients received cephazolin prophylaxis, and the remaining 5 patients received clindamycin and gentamicin. In addition to vaginal hysterectomy, 29 patients underwent reconstructive pelvic surgery, including 29 vaginal vault suspensions, 25 rectocele repairs, 10 bilateral salpingo-oophorectomies and 23 tension-free vaginal-tape suburethral slings. The remaining two patients had a vaginal hysterectomy alone. The average parity in the group was 3.26 ± 2.0, and the average body mass index was 29.3 ± 7.7 kg/m^2. In total, 25 patients (81%) in the study group were Caucasian, and the remaining six patients (19%) were African-American; Fifteen patients (48%) in the group were postmenopausal, and four of these women were taking combined oral hormone replacement therapy at the time of surgery.

Baseline cultures revealed normal vaginal flora in all cases (Table 1). None of the baseline cultures were negative and, as expected, a wide variety of aerobic and anaerobic pathogens was found.

Figure 1 shows that the highest total colony counts were found at the first intraoperative time interval (i.e. 30 minutes after completion of the surgical scrub). Anaerobic bacteria were equally suppressed throughout all culture groups (Figure 2).

On the first set of cultures (i.e. 30 minutes after the surgical scrub), 52% (16/31) of patients had ≥ 5000 colonies of bacteria present. In total, 29 operations lasted long enough to result in a second set of cultures, and 41% (12/29) of these cultures revealed ≥ 5000 bacterial colonies. A third set of cultures (150 minutes after the surgical scrub) was collected in 24 patients, and 25% (6/24) of these

Table 1 Bacteria found in baseline (preoperative) vaginal cultures

Bacteria type	*Proportion of patients (n = 1) with given bacteria type on baseline culture*
Anaerobic pathogens[a]	45% (14/31)
Coagulase-negative *Staphylococcus aureus*	58% (18/31)
Staphylococcus aureus	16% (5/31)
λ-Hemolytic streptococci	10% (3/31)
α-Hemolytic streptococci	23% (7/31)
Enterococcus faecalis	10% (3/31)
Escherichia coli	42% (13/31)
Gram-negative bacilli[b]	13% (4/31)
Lactobacilli	87% (27/31)
Klebsiella pneumoniae	13% (4/31)
Group B streptococci	13% (4/31)
Coryneforms	13% (4/31)

[a]Includes *Peptostreptococcus, Bacteroides, Clostridium perfringens* and *Prevotella meloninogenica*; [b]Includes *Alcoligenes, Enterobacter, Serratia* and *Proteus*

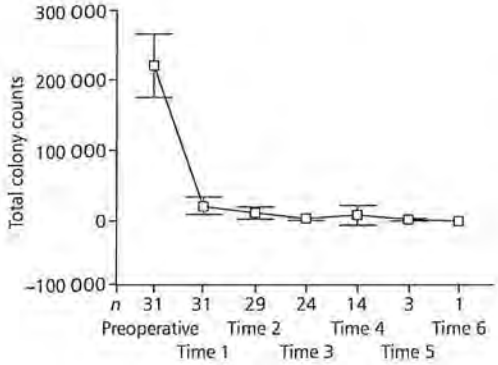

Figure 1 Total colony counts including all bacteria as a function of intraoperative time. Error bars represent 95% confidence intervals. Time 1 = 30 minutes after povidone–iodine preparation. Time 2 = 1 hour after time 1. Each subsequent time is 1 hour after the previous one

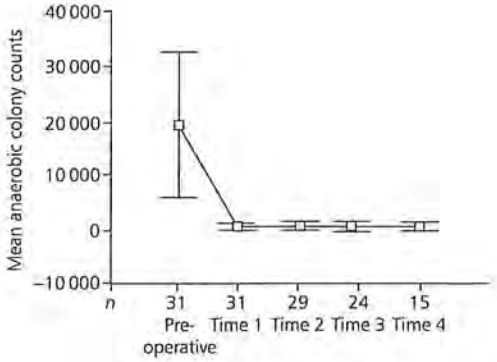

Figure 2 Anaerobic bacterial colony counts as a function of intraoperative time. Error bars represent 95% confidence intervals. Time 1 = 30 minutes after povidone–iodine preparation. Time 2 = 1 hour after time 1. Each subsequent time is 1 hour after the previous one

were contaminated. Of the 14 patients for whom a fourth set of cultures was obtained, only two (14%) were contaminated, and none of the subsequent cultures for any patient contained ≥ 5000 colonies.

At each intraoperative time interval, some of the patients' cultures were completely negative. This occurred in 29% (9/31) of the first set of cultures, 35% (10/29) of the second set, 42% (10/24) of the third set and 86% (12/14) of the fourth set.

None of the 31 patients developed operative site infections.

DISCUSSION

All of the successful techniques for infection prophylaxis have one thing in common – they decrease the number of bacterial colony counts at the operative site. These techniques have worked so well for gynecologic cases that it is no longer feasible to use actual infections as the outcome measure for future studies of infection prophylaxis. Therefore a surrogate end point such as peri-operative bacterial colony counts would be useful. Presumably any intervention that could decrease the number of bacteria present in the operative field would also reduce the rate of operative site infections.

This is the first description of the bacterial colony counts present in the operative field before and during vaginal surgery when standard infection prophylaxis is used. The strengths of this study include the relatively homogenous population and the standardization of specimen collection and processing.

Despite strict adherence to the aseptic protocol, the highest bacterial colony counts were found 30 to 90 minutes after the surgical scrub, possibly implicating the latter as the 'weakest link' of standard infection prophylaxis protocols. Thereafter, mean bacterial colony counts decreased sharply, possibly due to the preoperative antibiotics. Therefore any future interventions designed to minimize intraoperative bacterial colony counts should focus on the first 30 to 90 minutes of the operation. Perhaps the use of a different surgical scrub preparation and/or antibiotic regimen would be a more effective way to prepare the vaginal field for surgery, by further reducing colony counts during the first 90 minutes of surgery.

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Safety considerations for synthetic sling surgery

Jerry G. Blaivas, Rajveer S. Purohit, Matthew S. Benedon, Gabriel Mekel, Michael Stern, Mubashir Billah, Kola Olugbade, Robert Bendavid and Vladimir Iakovlev

Abstract | Implantation of a synthetic midurethral sling (SMUS) is the most commonly performed anti-incontinence operation in women worldwide. The effectiveness of the SMUS is comparable to that of the historical gold standards—autologous fascial slings and the Burch colposuspension. Much controversy, however, has evolved regarding the safety of this type of sling. Overall, the quality of the studies with respect to assessing risks of SMUS-associated complications is currently poor. The most common risks in patients with SMUS include urethral obstruction requiring surgery (2.3% of patients with SMUS), vaginal, bladder and/or urethral erosion requiring surgery (1.8%) and refractory chronic pain (4.1%); these data likely represent the minimum risks. In addition, the failure rate of SMUS implantation surgery is probably at least 5% in patients with stress urinary incontinence (SUI). Furthermore, at least one-third of patients undergoing sling excision surgery develop recurrent SUI. Considering the additional risks of refractory overactive bladder, fistulas and bowel perforations, among others, the overall risk of a negative outcome after SMUS implantation surgery is ≥15%.

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Introduction

The Burch colposuspension and autologous fascial pubovaginal sling have been considered the gold standard treatments of stress (sphincteric) incontinence (SUI), in women since the late 1990s.[1] Historically, pubovaginal slings had been reserved for women with complicated, severe and/or recurrent sphincteric incontinence,[2] but since the late 1990s these have been advocated for treatment of women with all types of sphincteric incontinence—simple and complicated.[3,4] Over the past decade, fueled by a stampede of innovations in synthetic sling composition, structure and implantation techniques and a surge in commercial marketing, implantation of the synthetic midurethral sling (SMUS) has emerged as the most frequently performed operation in women with SUI. Some authors suggest that, to date, over 3 million SMUS implantation procedures have been conducted worldwide, and more than 80% of these happened in the USA.[5] We have been unable to independently verify the number of SMUS implanted worldwide. But, by extrapolating the data from a population-based cohort study,[6] we estimate that approximately 500,000 SMUS were implanted in the USA between years 2001–2010 and that in the ensuing 4 years at least another 300,000 of these procedures were done. Considering the size of the population of the rest of the world and the fact that slings have been implanted *en masse* in most economically developed countries since at least the mid-1990s, a figure of 3 million procedures seems reasonable.[6] Furthermore, in an analysis of 7,200 case logs submitted by American urologists for their certifying credentials in 2013, 83% of operations performed for incontinence in women were SMUS implantations.[7]

SMUS implantation is an operation for the correction of sphincteric incontinence in which a synthetic plastic like mesh strip (the sling) is passed around the urethra into the retropubic space or beneath the urethra through the obturator foramen using trocars. Theoretically, when abdominal pressure rises, as in a cough or sneeze, the urethra is compressed by the sling, and the flow of urine is prevented, much like kinking of a garden hose. The appeal of such procedures is obvious—in theory. SMUS implantation is a minimally invasive, easy-to-perform procedure that is usually completed in under half an hour and, compared to traditional native tissue repairs, enables a much faster recovery with less perioperative morbidity than either the Burch colposuspension or autologous fascial slings. The effectiveness of this approach remains unchallenged. Numerous trials have shown SMUS to be as effective as the autologous fascial sling and Burch colposuspension, with moderate and/or high quality of evidence.[8]

Theory and practice often diverge, though, and this seems to be the case with SMUS. As more SMUS implantations are being performed and the longevity expectations of patients with SMUS are increasing, it has become apparent that unanticipated, serious, sometimes lifestyle-altering complications can occur that are not only unique to patients with SMUS but are also often refractory to treatment.[9,10] The purpose of this Review is to summarize the published literature regarding complications that are uniquely associated with SMUS and to present an overview of complications that are not unique to these slings.

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Competing interests
J.G.B. and V.I. have provided opinions as medicolegal expert witnesses in mesh litigation cases. J.G.B. has acted as a consultant for Astellas Pharma, is a shareholder in P Square Medical, and is a shareholder and co-owns intellectual property with LLC and Symptelligence Medical Informatics. The other authors declare no competing interests.

Key points

- The effectiveness of synthetic midurethral slings (SMUS) is comparable to the time-honoured gold standards—the autologous fascial sling and Burch colposuspension
- At least 15% of women with SMUS experience a serious adverse outcome and/or recurrent sphincteric incontinence
- A subset of women sustain refractory, lifestyle-altering complications that are unique to women with a SMUS
- SMUS-associated complications are under-reported
- The overall quality of the published evidence is currently low with respect to assessing SMUS safety and SMUS-associated complications

Transvaginal mesh slings

The retropubic tension-free transvaginal mesh tape (RP) sling procedure was introduced for treatment of SUI in 1995,[11] and was soon followed in 2001 by the transobturator tape (TOT) sling procedure, in which the sling is introduced via the obturator fossa instead of the retropubic space in an attempt to minimize the complications associated with use of RP slings.[12] Since the introduction of these procedures, results of many modifications of the RP and TOT sling procedures have been published, generally with a follow-up duration of <4 years; most studies had a follow-up duration of ≤1 year.

In a review of prospective randomized controlled trials investigating performance of RP and/or TOT slings, authors reported objective cure rates of patients treated with RP slings ranging between 83.9% and 100%, and 84% and 97.6% for those with TOT slings. Subjective cure rates for patients with RP or TOT slings were 64.5–94% and 60–92.9%, respectively. Median or mean follow-up duration of these studies ranged between 9 months and 24 months.[13] Thus, no notable differences in effectiveness have been revealed by meta-analyses of trials comparing the effectiveness of RP slings with that of TOT slings.[14,15]

More than 19 years have elapsed since the introduction of RP slings and 13 years for TOT slings; results regarding the long-term effectiveness of these treatments are, therefore, now available, with the longest series reporting a follow-up duration of 17 years.[16] Findings of over 200 studies of varying design and quality, investigating the effectiveness of either RP or TOT slings have been published. Of these, only six contain information on outcomes of patients followed up for >5 years and five have reported outcomes after a follow-up duration of 5 years (Table 1). Effectiveness of the treatments tested in these studies has been measured using a variety of subjective and/or objective outcome instruments. Subjective outcomes have been measured using detailed validated questionnaires such as the short urogenital distress inventory (SUDI), short incontinence impact questionnaire, the European quality of life questionnaire,[17] the patient global impression of improvement (PGII) questionnaire,[16,18] the visual/verbal analogue scale (VAS),[16,19–21] non-validated questionnaires[20,22] and telephone surveys.[23] In our judgement, however, the use of some of the validated outcome instruments does not provide sufficiently explicit data to be considered scientifically rigorous. For example, the urogenital distress inventory (UDI)-6 conflates bother with incontinence. This inventory contains the question "Do you experience and how much are you bothered by … leakage,"[24] from stress incontinence? This means a woman could leak only a few drops once a year and have a lot of bother or be totally incontinent and have no bother, yet record exactly the same score. Furthermore, variability in the use of validated and nonvalidated questionnaires might be another explanation of the discrepancies in reported outcomes and can complicate direct comparisons of results from different studies.

A variety of objective outcome instruments have also been used to measure outcomes of these long-term (follow-up duration ≥5 years) studies. The Valsalva stress test, in which the patient is asked to perform a Valsalva manoeuvre to increase abdominal pressure, or the cough test with a full bladder to provocatively test for the development of SUI are the most commonly used objective outcome measures.[17,18,20,21] However, these tests are not standardized and, typically, abdominal and vesical leak point pressures are not measured.[25] Other studies involved checking bladder volume by ultrasonography or just verbally confirming that the patient feels that their bladder is "comfortably full"[26] or "full"[18,27] and then asking the patient to cough. One group asked the patient to do "20 jumping jacks and 3 forceful coughs"[22] or "10 coughs in the standing position"[22] with a 300 ml bladder volume to check for SUI.[22]

The pad-weight test is another objective measurement used to assess treatment outcomes. A variety of pad-weight tests were used in these long-term studies including a 1-hour pad-weight test,[19] a 24-hour pad-weight test[28] and a 48-hour pad-weight test[29] with a result of ≤1 g increase in pad weight defining cure. Two studies used urodynamic evidence of the absence of leak on performing a Valsalva manoeuvre to indicate post-operative success either as a primary endpoint or as an adjunctive measure.[17,18]

Of published series with follow-up durations ≥5 years, the largest consisted of 707 patients and the smallest consisted of 55 patients.[16–23,26,27,29] Overall, objective cure rates of patients with SUI after treatment with either TOT or RP slings at or after a follow-up duration of 5 years ranged between 71% and 92%, and subjective cure rates between 65% and 90.3%. By combining subjective measures of cure and improvement, treatment effectiveness increased from 76% to 95% (Table 1).[16–23,26,27,29]

The series with the longest reported follow-up duration (17 years) was a prospective, single-institution study of 90 women who underwent the (original) RP sling implantation procedures at Uppsala University.[16] The overall rate of subjective cure or improvement assessed using the PGII score was 87% and the objective cure rate assessed using a cough stress test was 91%. Between follow-up years 5 and 17, objective cure rates declined very little—from 94% to 91%—and subjective cure or improvement decreased from 95% to 87%. However, 11 of 53 evaluable patients said that they

Table 1 | Long-term (follow-up duration >5 years) studies of SMUS effectiveness

Study characteristics	Patient characteristics	Mean follow-up duration (months)	Outcome Instrument	Outcomes*
Prospective studies				
Angioli *et al.* (2010)[20] *n*=72	Outcomes of 69 patients with RP or TOT slings were evaluated; 4.1% were lost to follow up	60	ST, NVQ,‡ VAS‡	Objective cure reported in 71% and 73% in patients with RP or TOT slings, respectively; Subjective cure reported by 60% and 62% of patients with RP or TOT slings, respectively
Groutz *et al.* (2011)[23] *n*=60	Outcomes of 52 patients with RP slings were evaluated; 13.3% were lost to follow up	60	NVQ‡	Subjective cure reported by 65% of patients
Groutz *et al.* (2011)[27] *n*=65	Outcomes of 61 patients with TOT slings were evaluated; 6.1% were lost to follow up	60	ST, NVQ‡	Objective cure reported in 74% of patients, 8% had improved symptoms and 18% subjectively reported treatment failure
Cheng *et al.* (2012)[17] *n*=103	Outcomes of 100 patients with TOT slings were evaluated; 2.9% were lost to follow up	65	VUD, QOL,‡ VAS‡	Objective cure reported in 87.4% of patients; subjective cure reported by 78% of patients
Nilsson *et al.* (2013)[16] *n*=90	Outcomes of 58 patients with RP slings were evaluated; 23.3% were lost to follow up	201	ST, VQ‡	Objective cure reported in 91.3% of patients; subjective cure reported by 87%
Serati *et al.* (2013)[18] *n*=191	Outcomes of 185 patients with TOT slings were evaluated; 3.1% were lost to follow up	60	ST, VQ‡	Objective cure reported in 90.3% of patients; subjective cure reported by 90.8%
Svenningsen *et al.* (2013)[22] *n*=603	Outcomes of 483 patients with RP slings were evaluated; 19.9% were lost to follow up	120	Exercise+PT, VQ,‡ NVQ‡	Objective cure reported in 89.9% of patients; subjective cure reported in 76.1% of patients; 18% had improved symptoms; 5.9% had treatment failure
Retrospective studies				
Ankardal *et al.* (2006)[29] *n*=707	Outcomes of 271 patients with RP slings were evaluated; 5.0% were lost to follow up	60§	ST, 48 h PT (NVQ,‡ VAS‡)	Objective cure reported in 83% of patients; subjective cure reported by 73.1% of patients; 15.9% had improved symptoms; 11% had treatment failure
Olsson *et al.* (2010)[21] *n*=147	Outcomes of 104 patients with RP slings were evaluated; 15.6% were lost to follow up	138	ST	Objective cure reported in 84% of patients; subjective cure reported by 77% of patients; 18% had improved symptoms; 5% had treatment failure
Li *et al.* (2012)[19] *n*=55	Outcomes of patients with RP slings were evaluated; percentage of patients lost to follow up not reported	81.85	1 h PT (NVQ‡)	Objective cure reported in 85.5% of patients; subjective cure reported in 74.6% of patients; 7% had improved symptoms; 25.6% had treatment failure
Athanasiou *et al.* (2014)[26] *n*=145	Outcomes of 124 patients with TOT slings were evaluated; 14.4% were lost to follow up	90.3	ST (VQ‡)	Objective cure reported in 81.5% of patients; subjective cure reported in 83.1% of patients; 3.2% had improved symptoms; 13.7% had treatment failure

*Owing to a lack of uniformity in reporting efficacy (improved and failed), improvement and failure were assumed to be based on subjective responses. Incidence of failure was calculated by subtracting the sum of subjective cured and improved responses from 100%. Improved patients were mutually exclusive to cured patients reported. ‡Indicates a subjective outcome instrument. §Indicates actual, not mean follow-up duration. Abbreviations: NVQ, nonvalidated questionnaire; PT, pad-weight test; QOL, quality of life; RP, retropubic tension-free transvaginal mesh tape; SMUS, synthetic midurethral slings; ST, cough or valsalva stress test; TOT, transobturator tape; VAS, visual analogue scale; VQ, validated questionnaire; VUD, videourodynamics.

"experienced leakage during straining".[16] The authors attributed this symptom to the development of severe urge incontinence, which might or might not have been caused by the RP sling itself. However, this study was hindered by the fact that 32 of 90 patients (36%) were not included in the analysis after a follow-up duration of 17 years as 11 (12%) women died, five (6%) had mental impairment and 16 (18%) were lost to follow-up. Overall, 58 (64%) women were available to have their 17-year outcomes evaluated, of whom 46 (51%) women were evaluated in the clinic and 12 (13%) were interviewed by telephone.

By contrast, in another investigation,[30] researchers using much more stringent outcome criteria found the 2-year objective success rate of RP and TOT slings was 77% and 72.3%, respectively and the subjective success rates were 56% and 48%—nearly a 40% reduction in subjective success compared with results from the Uppsala cohort.[16] In this randomized study of 597 patients, objective success was defined as a negative provocative stress test, a negative 24-hour pad-weight test and no need for retreatment of SUI.[27] Subjective success was defined as the absence of self-reported symptoms of SUI on the Medical, Epidemiological and Social Aspects of Aging questionnaire and no urine leakage recorded in a 3-day voiding diary.

The overall effectiveness of RP or TOT slings reported in these long-term studies of patients with SUI has been generally high, although some of the reported success occurred after a secondary operative procedure or medical intervention.[17,19,21,26] Thus, for patients who developed mesh erosion and had successful revision surgery, studies would typically report this as a successful outcome. Secondary treatments for those who develop *de novo* urge incontinence have not been reported, although if the RP or TOT sling procedures are effective in these patients they would typically be included in the 'subjectively cured' or 'improved' category.

The percentage of patients who were lost to follow up should also be carefully noted. In patients who were lost to follow up because of death, the cause of death and

Table 2 | Complications of either RP or TOT slings

Complication	*n*	Complications (% of patients)	Incidence (mean; range)
General complications			
Death within 30 days*	7,762	0 (0.0)	0.0
Urethral obstruction/voiding dysfunction	25,586	1,403 (5.5)	7.3; 0–33.9
Urethral obstruction requiring surgery	9,375	301 (3.2)	2.3; 0–21.3
Urinary infections	13,296	598 (4.5)	7.3; 0–39.1
Pain (within 6 weeks)	5,097	374 (7.3)	7.9; 0–33.3
Neurologic symptoms (within 6 weeks)	1,769	42 (2.4)	1.2; 0–10.3
De novo OAB	14,765	1,512 (10.2)	10.9; 0–48.1
Pelvic organ perforation			
In total	20,630	681 (3.3)	3.5; 0–16.1
Bladder	19,411	579 (3.0)	2.9; 0–16.1
Vaginal	5,521	91 (1.6)	1.4; 0–14.1
Urethral	4,541	6 (0.1)	0.0; 0–1.5
Bowel	3,820	4 (0.1)	0.0; 0–1.7
Ureteral	3,820	1 (0.0)	0.0; 0–1.3
Mesh exposure/erosion/extrusion			
In total	17,520	475 (2.7)	2.5; 0–26.1
Treated conservatively	15,403	112 (0.7)	0.9; 0–7.1
Vaginal	13,496	78 (0.6)	0.7; 0–7.1
Bladder	13,496	5 (0.0)	0.0; 0–5.6
Urethral	13,496	0 (0.0)	0.0
Requiring surgery	16,619	333 (2.0)	1.8; 0–26.1
Vaginal	13,705	235 (1.7)	1.5; 0–15.9
Bladder	13,393	29 (0.2)‡	0.2; 0–15.2
Urethral	13,628	11 (0.1)	0.2; 0–16.7
Longer-term complications			
Refractory pain (>6 weeks)	7,084	247 (3.5)	4.1; 0–30.5
Neurologic Symptoms (>6 weeks)	2,449	51 (2.0)	1.0; 0–10.6
Fistulas	710	2 (0.3)	0.3; 0–1.1

*No deaths were reported in peer-reviewed publications, although 7 were reported in the MAUDE database. ‡Three studies removed from incidence calculation because these were case series of just bladder erosions. Abbreviations: MAUDE, manufacturer and user facility device experience; OAB, overactive bladder; RP, retropubic tension-free transvaginal mesh tape; TOT, transobturator tape.

whether it might have been related to having a TOT or RP sling has not been reported. In addition, long-term studies often featured a lack of follow up in a substantial number of patients. In these long-term studies, between 5% and 36% of patients were either deceased or unavailable for follow up for other reasons (Table 1).

In summary, the long-term effectiveness of RP or TOT slings, as measured by subjective and/or objective instruments suggests that rates of cure or improvement of SUI after implantation are high and compare favourably to the traditional gold standard—the autologous pubovaginal sling. These results might, however, be overly optimistic owing to a host of factors including the suboptimal outcome instruments used, inclusion of patients who might have required multiple procedures and the loss of a substantial number of patients to follow-up monitoring.

SMUS complications

Mesh sling complications can be caused by a host of factors: intraoperative transgressions (such as viscus or vaginal perforation and nerve injury);[31] bacterial contamination;[32] improper tensioning of the sling—either too tight or too loose; host–foreign-body reaction;[33] tissue ingrowth;[34,35] and changes that the mesh undergoes once implanted, such as degradation, curling, banding and leaching of substances into the surrounding tissues (Tables 2–5).[36–38]

Evaluating the incidence, severity and consequences of the various RP and/or TOT sling complications is a daunting task. Of the thousands of published studies, only a few were even designed to track complications in any meaningful way. The short follow-up duration of most of these studies and the lack of accounting for those lost to follow up are additional confounders. In addition, complications might arise that were not even recognized when the original studies were conducted, such as banding as a cause of dyspareunia, which was first described in 2010.[38] Furthermore, all studies are hampered by an absence of the patient's own perception of the severity of the complication. For example, one study[39] that included pain lasting >6 weeks as a category of complication was published, but there is no mention of the severity of this pain, effect on quality of life nor how long the pain actually lasted. For some patients, this pain is treatment-refractory and lifestyle-altering, yet no metric exists that describes this category of complication in sufficient detail. The effects of long-term pain receive no attention at all in any study except for a few case studies of complications.[9,40–44]

The concomitant, widespread use of two different generic sling designs (RP and TOT) with different implantation techniques and at least 41 different commercially available kits,[42] each having different sling and trocar characteristics with potentially different complication profiles, confounds accurate analysis of sling complications. These different characteristics might also portend different complication profiles, yet studies of sling complications almost never distinguish between the different kit types and many do not even separate TOT from RP slings.

Considerable evidence exists that SMUS complications are underreported. Discrepancies exist between the SMUS complication rates reported by urologists from individual institutions, those reported in the literature, the (unreported) experience of tertiary care practices and those in the MAUDE (Manufacturer and User Facility Device Experience) database.[10,40,45] For example, in a population-based cohort of 45 million commercially insured individuals in the USA, investigators found the cumulative risk of requiring sling removal owing to voiding dysfunction or mesh extrusion and/or erosion to be 3.7% (95% CI 3.5–3.9%) after a follow-up duration of 9 years.[6] Furthermore, this study[6] excluded patients whose slings were removed owing to pain and other indications, thus the actual incidence of sling removal owing to complications is probably even higher than that. Extrapolating from this estimate and the estimated number of slings implanted in the

Table 3 | Complications of RP slings

Complication	*n*	Complications (% of patients)	Incidence (mean; range)
General complications			
Death within 30 days	3,499	0 (0.0)	0.0
Urethral obstruction/voiding dysfunction	16,301	704 (2.8)	8.8; 0–32.7
Requiring surgery	6,875	223 (2.4)	2.7; 0–8.9
Urinary infections	8,936	327 (3.7)	8.6; 0–39.1
Pain (within 6 weeks)	2,133	111 (5.2)	4.5; 0–23.1
Neurologic symptoms (within 6 weeks)	520	14 (2.7)	1.6; 0–5.0
De novo OAB	7,989	925 (11.6)	11.4; 0–29.4
Pelvic organ perforation			
In total	13,164	498 (3.8)	4.8; 0–14.3
Bladder	12,929	480 (3.7)	4.6; 0–14.3
Vaginal	763	11 (1.4)	1.0; 0–2.1
Urethral	1,224	4 (0.3)	0.0; 0–1.5
Bowel	800	4 (0.5)	0.0; 0–1.7
Ureteral	800	0 (0.0)	0.0
Mesh exposure/erosion/extrusion			
In total	8,303	179 (2.2)	2.3; 0–26.1
Treated conservatively	7,168	44 (0.6)	0.1; 0–5.6
Vaginal	6,193	22 (0.4)	0.0; 0–4.6
Bladder	6,193	5 (0.1)	0.0; 0–5.6
Urethral	6,193	0 (0.0)	0.0
Requiring surgery	7,902	135 (1.7)	1.6; 0–26.1
Vaginal	6,621	79 (1.2)	1.0; 0–10.9
Bladder	6,386	26 (0.4)	1.4; 0–15.2
Urethral	6,621	4 (0.1)	0.3; 0–16.7
Longer-term complications			
Refractory pain (>6 weeks)	2,328	42 (1.8)	2.0; 0–7.9
Neurologic symptoms (>6 weeks)	908	19 (2.1)	1.0; 0–5.2
Fistulas	388	1 (0.2)	0.4; 0–0.7

Abbreviations: OAB, overactive bladder; RP, retropubic tension-free transvaginal mesh tape.

USA (80% of 3 million slings worldwide),[5] approximately 88,000 removal procedures should have occurred, yet we could find only 740 such procedures that have been reported in peer-reviewed publications.[17,18,20,26,31,43,46–99] An additional 7,654 mesh removals are reported in patient series investigating sling complications.[6,9,10,41,44,100–114] Use of imperfect research methodologies, a lack of long-term follow up and reporting bias have been suggested as causes of these differences.[10,45,115,116]

Safety and risk:benefit considerations

Safety of SMUS surgery refers to the probability of any adverse event, while risk describes the range and probability of specific adverse events. Demonstrating risk is relatively easy, but assessing safety is much more difficult. Any known adverse event is a risk, regardless of how infrequently the event has been reported or observed. Even a single case report of an adverse event establishes the existence of a specific risk, although without knowing the denominator, accurate assessments of the safety of sling surgery are impossible. The problem, simply stated, is that no well-controlled long-term safety studies with published results currently exist, nor do any good registries in this area. In lieu of this lack of conclusive evidence, we present current data, which, at its best, represent the minimum risks associated with SMUS implantation and long-term use (Tables 1 and 2). Major risks of SMUS surgery, which should be weighed up by patients considering undergoing these procedures, include those requiring further surgery and those that are refractory to treatment. Complications that lead to further surgery include urethral obstruction (3.2%), vaginal, bladder and/or urethral erosion (2%) and fistulas (0.3%). In addition, we estimate that bowel perforation and serious infections have a combined incidence of about 0.1%.[117–134] Refractory and potentially lifestyle-altering complications include chronic pain (4.1%) and *de novo* overactive bladder (OAB) in 11% (Table 5), although the number of patients with *de novo* OAB who are refractory to treatment remains unknown. Evidence suggests that well over 50% of patients with OAB of any aetiology discontinue medical treatment within 1 year, owing to a combination of poor effectiveness and low tolerability.[135–137] For the purposes of this discussion we made a conservative estimate that 35% of patients with *de novo* OAB following SMUS surgery are refractory to treatment, which suggests that approximately 3.9% of patients who have undergone SMUS surgery will have refractory OAB (Box 1).

Establishing safety, defined as the chances of having an unsatisfactory outcome following sling surgery, is an important step in enabling accurate patient decision making. Many patients with both chronic pain and *de novo* OAB have previously undergone SMUS revision surgery; however, simply adding together the complication incidences to give an accurate indication of safety is impossible, as the available data are not sufficiently reliable to produce an accurate estimate this way. For the purposes of this discussion, we have made our best estimate of the safety of SMUS surgery utilizing the data summarized in the preceding paragraph.

The reported 5-year failure rate of SMUS surgery in patients with SUI ranges from 5% to 26% (Table 1),[16–23,26,27,29] and the reported incidence of *de novo* SUI after sling excision surgery ranges from 10–62%.[9,43,78,84,85,94,100,138] From these data, we estimate the lowest rate of recurrent and/or persistent SUI among patients who underwent SMUS surgery to be 5.3%. Furthermore, we conclude that the lowest estimated risk of serious complications of SMUS surgery is 13.6% and the additional risk of failure with respect to the original procedure (with respect to SUI) is 5.3%. These estimated data reflect the minimum risks reported in the literature, the actual risks could be considerably higher.

The ability of both physicians and patients to make informed decisions regarding sling surgery is predicated on an accurate understanding of the risk:benefit ratio. The benefits of sling surgery, with respect to effectiveness, have been well documented. By contrast, the risks associated with SMUS surgery are poorly understood

Table 4 | Complications of patients with a TOT sling

Complication	*n*	Complications (% of patients)	Incidence (mean; range)
General complications			
Death within 30 days*	4,044	0 (0.0)	0.0
Urethral obstruction/voiding dysfunction	8,287	406 (4.9)	5.9; 0–33.9
Requiring surgery	5,001	75 (1.5)	2.0; 0–21.3
Urinary infections	4,003	226 (5.6)	6.2; 0–23.3
Pain (within 6 weeks)	2,964	262 (8.8)	10.2; 0–33.3
Neurologic symptoms (within 6 weeks)	1,249	28 (2.2)	0.9; 0–10.3
De novo OAB	6,215	519 (8.4)	10.3; 0–48.1
Pelvic organ perforation			
In total	5,856	143 (2.4)	2.3; 0–16.1
Bladder	4,872	60 (1.2)	1.1; 0–16.1
Vaginal	4,582	80 (1.7)	1.6; 0–14.1
Urethral	4,296	2 (0.0)	0.0; 0–0.3
Bowel	3,020	0 (0.0)	0.0
Ureteral	3,020	1 (0.0)	0.0; 0–1.3
Mesh exposure/erosion/extrusion			
In total	8,293	196 (2.4)	2.7; 0–19.0
Treated conservatively	7,648	64 (0.8)	1.0; 0–7.1
Vaginal	6,739	52 (0.8)	1.0; 0–7.1
Bladder	6,739	0 (0.0)	0.0
Urethral	6,739	0 (0.0)	0.0
Requiring surgery	7,901	132 (1.7)	1.9; 0–15.9
Vaginal	6,528	98 (1.5)	1.8; 0–15.9
Bladder	6,528	3 (0.0)*	0.0
Urethral	6,528	7 (0.1)	0.0; 0–2.6
Longer-term complications			
Refractory pain (>6 weeks)	4,756	204 (4.3)	5.3; 0–30.5
Neurologic symptoms (>6 weeks)	1,541	32 (2.1)	0.9; 0–10.6
Fistulas	322	1 (0.3)	0.2; 0–1.1

*Case series only investigating bladder erosions were removed from the analysis. Abbreviations: OAB, overactive bladder; TOT, transobturator tape.

and poorly documented. Some risk factors, such as prior pelvic radiation or surgery, concomitant urethral diverticular surgery, the surgical learning curve and an individual surgeon's skill set are accepted risk factors, yet even these risk factors are not well documented in peer-reviewed publications. Thus, accurately prognosticating the risks of SMUS surgery for any particular patient is difficult.

Owing to the limitations inherent in the evaluation of risk and safety described in this section, we can estimate that, based on the available literature reports, a minimum of 12.5% of women who undergo mesh SMUS surgery have a serious adverse event and/or surgical failure, although limited data are available on prognostic indicators.

Perioperative complications

Methods used to identify and classify perioperative complications vary widely between studies. A classification system originally devised in 2004 based on severity of complications[139] was modified for use by the Urinary Incontinence Treatment Network, a multicentre collaboration supported by the National Institute of Diabetes and Digestive and Kidney Diseases, a branch of the NIH.[30,39,140,141] Investigators in this network defined minor complications (or minor adverse events) as those not requiring surgical intervention that were treated expectantly or with medication (grade 1–2). Major complications (serious adverse events) include those requiring one or more surgical procedures, and life-threatening complications are defined as those requiring management in an intensive care unit and often resulting in patient death (grade 3–5).[30] Bladder or urethral trocar perforation was considered to be a serious adverse event whether or not further intervention was necessary. Another classification scheme, the Accordion system,[120] enables postoperative complications to be categorized into in four levels of severity: mild, moderate, severe, and death.[44,142]

However, sorting complications into groups based solely on the severity of their presentation and treatment might be misleading in the absence of adequate follow-up monitoring. For example, patients with apparently minor complications such as vaginal exposure that is initially treated with local excision and primary closure might present with dyspareunia or recurrent exposure long after the follow-up period has expired.[9,31,41–44] Indeed, many patients in one of our own studies presented in exactly this way, but this fact was never captured in the paper owing to the methodology used.[9] We have seen many unreported examples of patients managed conservatively with short-term success, who ultimately presented with a recurrent complication that occurred after the study ended, owing to the short follow-up duration of most published research (1–2 years) relative to the expected lifespan of most implanted slings.[9,81,105,143–147] Authors of one study estimated the overall incidence of vaginal extrusion of mesh and pelvic pain to be 6% and 4.3%, respectively.[45] Despite peer-reviewed literature in this area being replete with statements about the short-lived nature of sling-related complications, most case reports of mesh sling complications document the treatment-refractory nature and suboptimal outcomes associated with these complications, none of which was captured by the original studies.[9,43] For some complications (cystitis, voiding dysfunction, pain or neurological symptoms), most authors claim that only expectant or medical treatment is necessary and that patient outcomes are satisfactory, without presenting any meaningful follow-up data to substantiate these claims.[30,146,148,149]

In 2011, the International Urogynaecology Association (IUGA) and the International Continence Society (ICS) published a joint recommendation for a standardization of terminology to report complications related to the insertion of prostheses and grafts in female pelvic floor surgery.[150] To date, these guidelines have not been widely used. The net result of all of this is that the science of assessing and reporting midurethral sling complications is seriously flawed.

Table 5 | Comparison of complications of patients with an RP sling or TOT sling

Complication	RP sling (mean; range)	TOT sling (mean; range)	Combined RP and TOT sling (mean; range)
General complications			
Death within 30 days	0.0	0.0	0.0
Urethral obstruction/voiding dysfunction	8.8; 0–32.7	5.9; 0–33.9	7.3; 0–33.9
Requiring surgery	2.7; 0–8.9	2.0; 0–21.3	2.3; 0–21.3
Urinary infections	8.6; 0–39.1	6.2; 0–23.3	7.3; 0–39.1
Pain (within 6 weeks)	4.5; 0–23.1	10.2; 0–33.3	7.9; 0–33.3
Neurologic symptoms (within 6 weeks)	1.6; 0–5.0	0.9; 0–10.3	1.2; 0–10.3
De novo OAB	11.4; 0–29.4	10.3; 0–48.1	10.9; 0–48.1
Pelvic organ perforation			
In total	4.8; 0–14.3	2.3; 0–16.1	3.5; 0–16.1
Bladder	4.6; 0–14.3	1.1; 0–16.1	2.9; 0–16.1
Vaginal	1.0; 0–2.1	1.6; 0–14.1	1.4; 0–14.1
Urethral	0.0; 0–1.5	0.0; 0–0.3	0.0; 0–1.5
Bowel	0.0; 0–1.7	0.0	0.0; 0–1.7
Ureteral	0.0	0.0; 0–1.3	0.0; 0–1.3
Mesh exposure/erosion/extrusion			
In total	2.3; 0–26.1	2.7; 0–19.0	2.5; 0–26.1
Treated conservatively	0.1; 0–5.6	1.0; 0–7.1	0.9; 0–7.1
Vaginal	0.0; 0–4.6	1.0; 0–7.1	0.7; 0–7.1
Bladder	0.0; 0–5.6	0.0	0.0; 0–5.6
Urethral	0.0	0.0	0.0
Requiring surgery	1.6; 0–26.1	1.9; 0–15.9	1.8; 0–26.1
Vaginal	1.0; 0–10.9	1.8; 0–15.9	1.5; 0–15.9
Bladder	1.4; 0–15.2	0.0*	0.2; 0–15.2
Urethral	0.3; 0–16.7	0.0; 0–2.6	0.2; 0–16.7
Longer-term complications			
Refractory pain (>6 weeks)	2.0; 0–7.9	5.3; 0–30.5	4.1; 0–30.5
Neurological symptoms (>6 weeks)	1.0; 0–5.2	0.9; 0–10.6	1.0; 0–10.6
Fistulas	0.4; 0–0.7	0.2; 0–1.1	0.3; 0–1.1

*Case series only investigating bladder erosions were removed from the analysis. Abbreviations: OAB, overactive bladder; RP, retropubic tension-free transvaginal mesh tape; TOT, transobturator tape.

Infection

In a randomized study of SMUS effectiveness, investigators found culture-proven cystitis in 8.4% of patients with RP and 4.7% with TOT slings.[30] In another study, the authors reported that 12% of patients developed at least one UTI in the first 3 months after RP sling surgery.[151] Our literature search documented bacterial cystitis in 0–39% of patients who underwent SMUS surgery (REFS 13,18,21–23,30,39,47,48,50,53,55–57, 59,61,66,74,76,83,91,152–186). Unfortunately, limited published data are available on the long-term consequences of these infections. For example, in one study, 7.3% of women had recurrent UTIs 12 months after being fitted with a TOT sling, but no published reports of longer-term follow-up currently exist.[76]

Other more serious infections have been reported after SMUS implantation. In a comprehensive literature review[45] several such complications following sling placement were reported: cellulitis;[117–121,187] abscess formation, including in the retropubic space,[122] retroperitoneal space,[123] thigh,[123] obturator space[124–126] and ischiorectal fossa;[127,128] sinus tract formation;[129] necrotizing fasciitis;[130] osteitis pubis;[131] and sepsis.[12] Thigh abscesses, a complication unique to the TOT sling approach, have been reported in the past decade.[101,123,188,189] Occurrence of such serious SMUS-related infectious complications is often delayed by months or years after sling implantation. Presenting symptoms include chronic discharge from the vagina, thigh and/or perineum.

Treatment of infected mesh and abscesses requires open drainage and removal of all mesh, which, otherwise, will serve as a nidus for further infection. Amid types II and III mesh materials,[190] such as Silastic® (Dow Corning, MI, USA) and Gore-Tex® (W.L. Gore & Associates, DE, USA), are easily identified and pulled out, usually in their intact form. The technical challenges of removing type I meshes are considerably greater. For example, even though the entire mesh is likely to be infected, only part of it is involved in the abscess. This part is easy to remove, but because of tissue ingrowth and probable degradation, the remaining mesh is usually embedded in the tissue and might fragment during dissection. Furthermore, the retropubic and thigh portions of RP and TOT slings, respectively, are notoriously difficult to remove.[9,43,78,84,85,94,100,138] RP slings are often adherent to the bladder neck and difficult to access during surgery. We, and others, have noted that the infection can track along muscle planes and even form a psoas muscle abscess in some patients.[123,191] These abscesses might require multiple operations in order to achieve a satisfactory outcome. Unfortunately, owing to the technical reasons explained above and concerns about complications in adjacent organs during the dissection, complete mesh removal is often not accomplished in patients with type I mesh slings. Necrotizing fasciitis (Fournier gangrene) has also been reported after both RP[192] and TOT[193] sling implantations. In patients with SMUS-related infections, removal of the complete mesh is particularly important. Of course, many more serious infectious complications are likely to arise from the 'minor' ones listed above,[113,126] but we could find no published studies that actually address this issue.

Pelvic organ perforations

Pelvic organ (bladder, urethral, vaginal [REFS 10,14, 16,18,21–23,30,33,39,47,48,50,52,53,55,56,59,62–64, 66,67,69–71,73,74,76,77,80,81,86–88,90–93,98, 99,109,132–134,140,145,146,148,151–153,156,158, 162,163,167,168,171,173,176–179,181–184,194–238], or bowel) perforation at the time of trocar passage has been reported to occur in 0–16% of sling surgery procedures (0–14% for RP sling implantation and 0–16% for TOT sling implantation). In most reports, the authors usually downplay any substantial implications of pelvic organ perforations. Authors will typically state that

Box 1 | Summary of mesh safety

Complications requiring surgery

- Urethral obstruction 3.2%
- Erosion, extrusion or exposure 2.0%
- Fistulas 0.3%
- Bowel injury or infection 0.1%
- Lifestyle-altering complications
- Chronic pain 4.3% (0.5%)*
- Refractory (*de novo*) OAB 11% (3.9%)*
- Recurrent and/or persistent SUI 5.3%
- Total incidence of serious complications and/or sling failure in patients with incontinence 15.3%

*Indicates numbers are not mutually exclusive to individual complications. For example, a patient who underwent mesh excision for exposure may develop refractory pain. The numbers in parenthesis refer to the estimated incidence of complications refractory to medical or surgical treament. Abbreviations: OAB, overactive bladder; SUI, stress urinary incontinence.

recognized trocar perforations of the bladder might be treated by simply removing the trocar (or sling) and passing it again and, at the discretion of the surgeon, leaving an indwelling catheter in for a matter of days or, sometimes, not at all.[148,239–242] However, in an article published in 2014, the authors concluded that occurrence of bladder and/or urethral perforations during surgery is associated with an almost 26-fold increase in risk of subsequent bladder or urethral mesh erosion.[31] If the findings of this study are accurate, the dictum of simply removing and repassing the trocar after bladder perforation must be seriously questioned.

Limited information is available on urethral complications following perforation, but if a perforation large enough to necessitate repair exists, most would agree that it is best to abandon the SMUS procedure.[39,62,64,73,140,213] Depending on the circumstances, buttressing the repair with a Martius flap in anticipation of performing an autologous or allograft sling procedure at another date is one possible approach; alternatively, in rare circumstances, when it is desirable to complete the surgery in one sitting, this could be done at the same time as sling implantation.[9,43,243] Such a situation might arise when a patient's health dictates that the risk:benefit ratio favours a single operation instead of two or, if the patient lives at a great distance from the treatment centre and returning for a second operation would present a major burden.

Bowel perforations during sling surgery are even more uncommon than perforations of other pelvic organs with a reported incidence in 0.005–0.02% of procedures.[132] In a meta-analysis published in 2007, authors reported a mortality rate of 20% in 35 incidences of bowel perforation during sling surgery.[133] Of particular concern is the fact that some patients did not present with any clinical signs of abdominal injury.[102,104,106,132–134,236] Patients' initial complaints were often originally attributed to voiding dysfunction and not until days later, when the patients became seriously ill, was the correct diagnosis made.[237] In five patients the diagnosis of bowel perforation during sling surgery was made only at autopsy.[238]

Voiding dysfunction

The term 'voiding dysfunction' was not clearly defined in the majority of studies in this area and could be interpreted as either voiding symptoms, storage symptoms or both. Some of the terms used include *de novo* or persistent overactive bladder, urgency or urge incontinence, urinary retention and urethral obstruction from SMUS. In addition, secondary voiding problems can arise after sling revision or excision surgeries performed to treat the original complications such as recurrent SUI, dyspareunia, urethral strictures and fistulas.[41,100,111,244] We used our best judgement to assign the authors' intent to one of the categories listed below, but in some instances the author's intent was not clear. For example, one category was listed as "voiding dysfunction requiring surgery",[30] although whether this was a result of urethral obstruction or refractory OAB was not defined. Keeping in mind the caveats listed above, temporary or refractory voiding dysfunction has been reported in 0–33% of patients with a SMUS, and is more common in patients fitted with an RP sling than in those fitted with a TOT sling (REFS 16–23,26,30,33,39,46,47,49–51, 53,54,56,58,59,61–66,68–71,73,74,76,77,79,80,82, 83,86–93,95,97–99,140,145,146,148,151–153,156–164, 166–171,173,174,176–184,186,194–205,207,208, 211,214–218,220,222–229,231–233,235,245–260).

OAB symptoms

The terms used to describe OAB in the studies reviewed included urge or urgency incontinence, urgency, refractory urgency and overactive bladder.[9,261] In addition, the qualifiers persistent or *de novo*[261] were often used. *De novo* OAB, indicating the occurrence of OAB after sling surgery, was reported in 0–48% of patients in various studies (REFS 17,18,20,26,39,46–48,50–53, 55,57–59,61,62,66,67,70,73–77,79,83,87,88,91,92, 96,97,99,140,152,153,155,157,159,161,163,164,166–168, 170–174,177,178,181–186,209,211,213,216–219,222, 224,228,229,231–235,245,249,254,255,259,262–269). Most patients with OAB had symptoms that were said to have resolved within the first month of surgery either spontaneously, or in response to anticholinergics, antibiotics or self-catheterization.[30,194] However, the metrics used to conclude this were inadequate for the task; in fact, the vast majority of studies used no metrics or validated outcome measures at all. When validated instruments were used, they were often, in our judgement, inadequate. For example, the UDI was one of the most common questionnaires used and, as alluded to above, conflates the degree of incontinence with bother.[24] Furthermore, the UDI contains no question that specifically refers to urgency (as opposed to urge incontinence). Approximately two-thirds of women with OAB do not have urge incontinence;[270] thus, use of this instrument is likely to miss two-thirds of the women with urgency or OAB in any series.

In patients with refractory OAB as a SMUS-related complication, a careful search for a remediable underlying aetiology should be conducted. Possible aetiologies include infection, stones, urethral obstruction

and mesh erosion into the bladder or urethra. When such aetiologies are found and treated, the reported success rates are generally high, but the methods used to determine treatment success were generally of poor quality. For example, in reports from two studies of endoscopic laser ablation of eroded mesh in patients with OAB the authors reported successful outcomes, but did not use any objective outcome measures.[100,108] Other studies did use validated instruments to quantify outcomes such as the Overactive Bladder Symptom Score, voiding diaries and pad-weight tests.[9] With these caveats in mind, a successful outcome after surgical treatment of these remediable conditions was reported in 28–64% of patients with refractory OAB as a SMUS-related complication.[9,30,43,85]

Urethral obstruction

Urethral obstruction is a urodynamic diagnosis based on high detrusor pressure accompanied by low urine flow rate, although again, no uniform criteria for diagnosing obstruction were used in the papers reviewed. Most investigators simply inferred obstruction based on the temporal relationship between SMUS surgery and voiding symptoms.[271,272] Others used measurements of urine flow rate and post-void residual volume or urodynamics. Urethral obstruction should be suspected in any woman with persistent voiding symptoms (either storage or emptying) after SMUS placement.[9,94,273,274] Obstruction is definitively diagnosed by the findings of high detrusor pressure and low uroflow during urodynamics. Generally, the existence of a normal urine flow rate is thought to exclude the presence of urethral obstruction; however, this is not always the case, as sometimes abnormal urine flow rate can be generated by a strong detrusor contraction or abdominal straining (Figure 1).

Even in the absence of urodynamically confirmed urethral obstruction, sling incision and/or excision can completely resolve refractory voiding (and OAB) symptoms. Compression from the sling is by far the most common cause of urethral obstruction, and at least one case of urethral stricture accompanied by urethral erosion has been reported.[9] The incidence of urethral obstruction requiring surgical intervention ranges from 0% to 8.9% in patients fitted with RP slings and from 0% to 21.3% for those with TOT slings (REFS 17,18,20,21,23,26,30,46–48, 50–56,58,59,61–64,66–69,71,74,77,80–83,86–92,97–99, 148,159,163,166,173,178,180–182,216–218,233,245,250, 253,255,258–260,269). In the largest patient series reported to date, which comprised nearly 190,000 SMUS implantation procedures, and was based on insurance data, a 9-year cumulative rate of sling revision surgery owing to urethral obstruction of 1.3% was reported. Most of this revision surgery occurred in the first few years after the original implantation procedure.[6] In this patient series, however, no mention of the number of patients lost to follow-up monitoring was made, and because investigators only searched for one Current Procedural Terminology (CPT) code (57287) for the sling revision surgery, the actual incidence of revision surgery owing to urethral obstruction was possibly higher. Similarly, a rate of urethrolysis of 3.4% was reported in a cohort of 818 patients fitted with RP slings, although investigators failed to search for 'mesh removal', 'explant' or 'excision'.[275] Owing to incomplete use of these search terms, retrospective studies of databases[6,270] are prone to underestimating the incidence of urethral obstruction requiring surgery.

The reported incidences of urethral obstruction requiring surgery are generally well under 10%. A small number of patients having urethral obstruction in the lost-to-follow-up group could substantially increase the actual overall incidence. In fact, most studies found that 50–75% (sometimes more) of patients undergoing sling revision surgery were treated by a surgeon other than the implanting surgeon.[9,44,276]

Some authors have recommended sling incision or even urethral dilatation for treatment of patients with urethral obstruction, although most authors agree that the entire suburethral portion of the sling should be removed, even if an incision into the wall or urethral lumen is required.[9,40,154,244,261] Whether to remove all of the mesh from RP slings in patients with urethral obstruction depends on multiple factors, including associated pelvic pain, dyspareunia and/or recurrent infections that might be related to retained mesh.[277–280] No meaningful data exist regarding the effectiveness of urethral dilatation; however, based on our clinical experience, we believe that this approach should not be used owing to the possibility of a urethral abrasion that might ultimately lead to erosion.[281] Of course, optical urethrotomy, internal urethrotomy and transurethral incision of urethral strictures should not be done at all except in the rarest of circumstances, for fear of causing iatrogenic urethral exposure.

No clear indications for urethrolysis currently exist; rather, the need for procedures of this type should be considered on a patient-by-patient basis, depending on the degree of scarring and urethral immobility.[282,283] In our judgement, urethrolysis should be considered in patients in whom the proximal urethra feels scarred and immobile during surgery and/or following a finding of limited urethral mobility on a Q-Tip® (Unilever, London, UK) test.

A high, and well documented incidence of recurrent SUI after mesh revision surgery exists, that is reported to range from 10% to 60% of patients who undergo revision surgery.[9,43,78,84,85,94,100,138] For each patient with symptoms of recurrent sphincteric incontinence, a decision needs to be made as to whether or not another anti-incontinence procedure should be considered. Reports of sling revision surgery in patients with sphincteric incontinence are sparse, and often anecdotal; but, if urethral reconstruction is necessary at the time of mesh removal, the AUA guidelines on the surgical management of female SUI[1] state that implantation of another SMUS are contraindicated in these patients. Most authors recommend a wait-and-see approach to management of patients with recurrent SUI after mesh revision surgery, and, as a rule, we agree with this

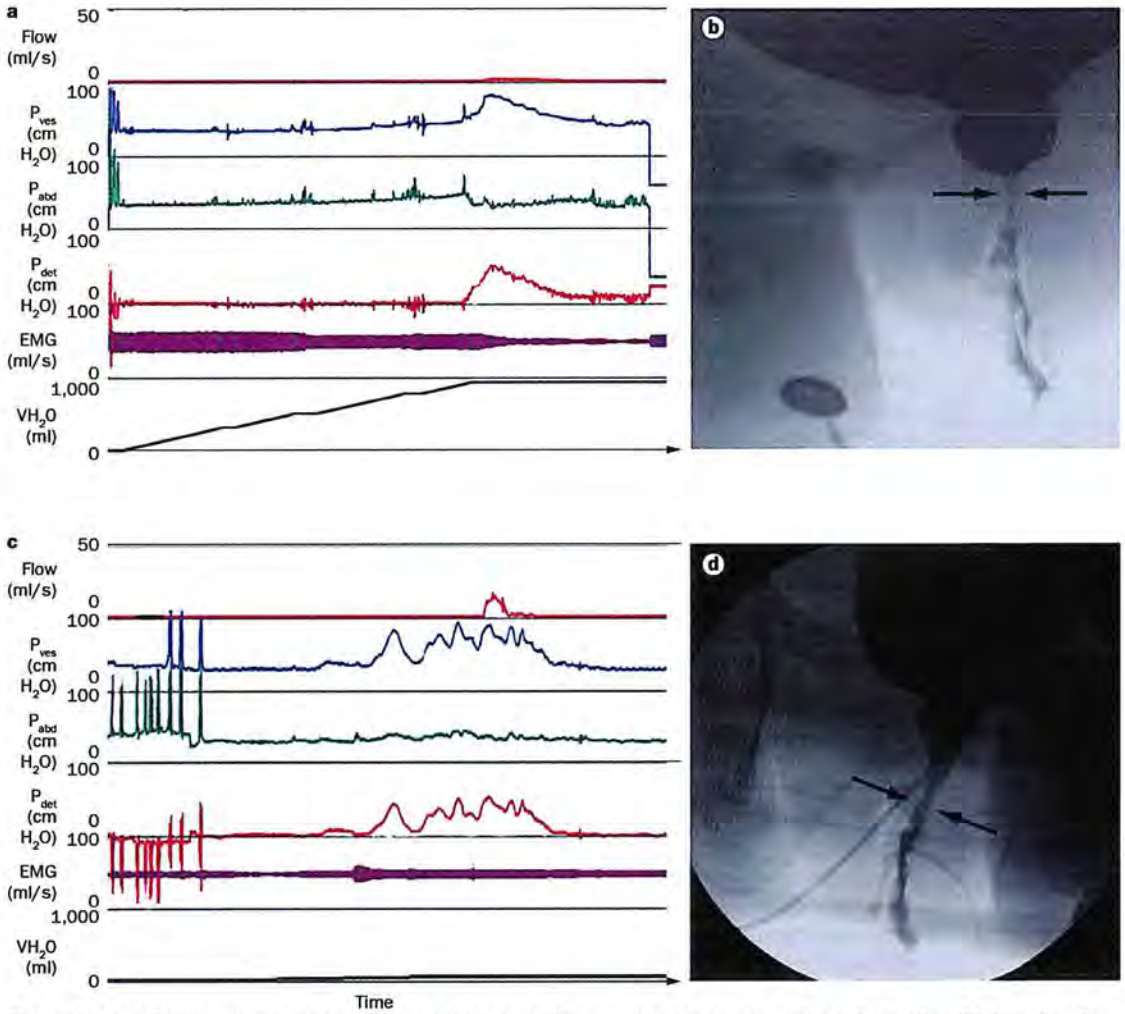


Figure 1 | Identification of urethral obstruction. **a** | Urodynamic trace showing severe urethral obstruction (Blaivas–Groutz nomogram type 2) caused by the presence of a urethral stricture in a 52 year-old woman 4 years postimplantation of a SPARC™ (American Medical Systems, MN, USA) SMUS. Urethral obstruction is confirmed by the presence of strong, sustained detrusor contraction ($P_{det}Q_{max}$ = 56 cm H_2O and Q_{max} = 1 mL/s). **b** | Cystourethrogram confirming the presence of an obstruction owing to the presence of a midurethral stricture (arrows). **c** | Urodynamic trace showing high-flow urethral obstruction in a 52 year-old woman 6 years after midurethral SMUS implantation. Urethral obstruction was confirmed by $P_{det}Q_{max}$ = 56 cm H_2O (Blaivas–Groutz nomogram type 1). Owing to a technical error, infused volume was not recorded on this trace. **d** | Voiding cystourethrogram showing the site of urethral obstruction to be in the distal third of the urethra (arrows). Abbreviations: EMG, electromyogram; P_{abd}, abdominal pressure; P_{det}, detrusor pressure; $P_{det}Q_{max}$, voiding pressure at peak flow; P_{ves}, intravesical pressure; Q_{max}, peak flow; SMUS, synthetic midurethral sling; VH_2O, bladder filling volume.

recommendation. However, data from two published reports contradict this recommendation. A continence rate of 71% was reported in 14 patients who underwent mesh removal after urethral perforations and, in another study, an 82% success rate after revision surgery was reported in 28 patients, of whom 14 had a synchronous autologous sling. In both series a Martius flap was placed between the urethra and sling.[9,43,243] No clear indications exist for conducting synchronous anti-incontinence surgical procedures during mesh excision surgery, although we believe that this approach should be considered whenever extensive damage to the proximal half of the urethra has occurred. Authors of most study reports, however, do not report thoroughly on the outcomes of sling excision surgery.

Mesh erosion, extrusion or exposure

Reports of research in this area of sling complications are typically replete with terminology that conflates the terms erosion, extrusion and exposure; thus, discerning the exact meaning of every author was often impossible. The joint recommendations of the IUGA and ICS[150] provide guidance regarding use of terminology related to SMUS complications, but, in a clinical sense, applying the recommended distinctions is usually not possible in most patients. The IUGA and ICS guidelines define exposure as "a condition of displaying (mesh), revealing, exhibiting, or making accessible for example through the vagina"[150] and extrusion of mesh as "passage gradually out of a body structure or tissue".[150] The guidelines also recommend avoiding use of the term 'erosion' altogether,

but in this Review, we use the terms interchangeably as there is no sound scientific way of making this distinction exists given that the overwhelming majority of authors use this terminology interchangeably. Conceptually, mesh can be seen to protrude through the vaginal wall or into the bladder, urethra or bowel by one of two mechanisms: either it was inadvertently positioned there at the time of surgery or somehow, over the course of time, the mesh gradually worked itself into such a position.

The incidence of mesh sling erosions varies widely between study reports, ranging from 0% to 41% of patients (REFS 16–20,22,26,30,31,39,46–50,52,53, 55–73,75–77,79,81,82,86–90,92,93,95–100,152,153, 155–160,162,164,166–179,181–185,204,207–209, 212–215,217–221,224,225,229,231,233–235,245,247, 252–255,257–259,265,266,268,284–293). The risk factors for sling erosion fall into three main categories: patient factors; mesh characteristics; and intraoperative considerations.[42] With respect to the patient, oestrogen-deficient states, genital atrophy, surgical scarring, concurrent prolapse surgery, type 1 or type 2 diabetes mellitus, steroid use, concurrent anticholinergic use and smoking have been reported as risk factors for sling erosion.[246] Patients ≥75 years of age also had a higher incidence of OAB and recurrent UTI[266] and patients of both younger and older ages (mean ages 55, and 75 years respectively) were variously reported as having adjusted risk factors. Previous pelvic radiation is another obvious risk factor for mesh erosion, but few of these patients undergo sling surgery; thus, this factor did not appear as such in the literature.

Certain types of mesh have a particularly high risk of erosion based on the intrinsic characteristics of the materials they are made from. In a study published in 1997,[190] synthetic materials used for herniorraphy (a type of hernia repair surgery) were categorized based on their composition (synthetic or biological), structure (monofilament or multifilament), pore size (macroporous or microporous) and architecture (knitted or woven). Type I (knitted, monofilament and macroporous polypropylene mesh) is currently considered to be the optimal SMUS mesh material owing to its large pore size (>75 μm), which facilitates infiltration of macrophages and fibroblasts, promotes neovascularity and tissue ingrowth, and minimizes the likelihood of infection. Examples of Type I mesh include VitaMESH™ (Atrium, NH, USA), Marlex® (C.R. Bard, NJ, USA), Prolene® (Ethicon, NJ, USA) and Trelex Natural® mesh (Boston Scientific, MA, USA).

In an attempt to decrease the foreign body responses associated with mesh materials and increase tissue compliance, several manufacturers have designed lightweight meshes of decreased density with smaller fibre diameter and larger pores, with the intention of preventing stiffness, contraction and mesh shrinkage. Several published studies purport some benefit of these new materials in patients requiring inguinal hernia repair; however, all of the studies involved small numbers of patients, with limited follow-up duration, thus precluding any meaningful conclusions.[35,294–300]

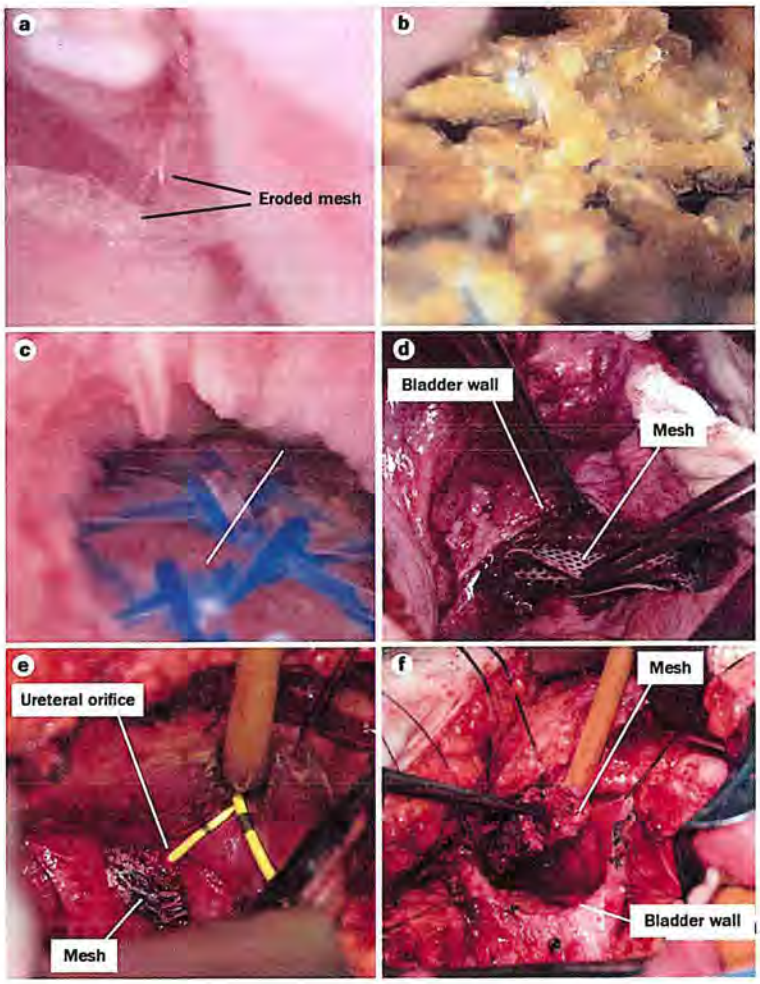
Amid type II mesh (monofilament and microporous) has pores (<10 μm in diameter) that are large enough to allow bacterial infiltration but too small for macrophage infiltration, thus infection is more probable and tissue ingrowth is impeded.[190] Polytetraflouethylene (PTFE, Gore-Tex® W.L. Gore & Associates, DE, USA) is the most common prototype type II mesh. Surgical Membrane Type III multifilament mesh is much denser and stiffer than other types of mesh and has interstices that are <10 μm in diameter with the same negative consequences as those of type II mesh. PTFE mesh (Teflon® DuPont, DE, USA), braided polyethylene terephthalate mesh (Mersilene® Ethicon, NJ, USA), braided polypropylene mesh (Surgipro™ [Covidien, CA, USA] monofilament mesh) and perforated PTFE patch (GORE® MYCROMESH® W.L. Gore & Associates, DE, USA) are examples of type III meshes. Type IV meshes are submicroporous coated biomaterials with pores <1 μm in diameter. SILASTIC® (Dow Corning, MI, USA), Celgard® polypropylene sheeting (Celgard, NC, USA) GORE® PRECLUDE® Pericardial membrane and GORE® PRECLUDE® Dura-substitute (both manufactured by W.L. Gore & Associates, DE, USA) are all type IV meshes. Types II–IV meshes, including PTFE mesh (Amid Type II), silicon-coated polyethylene or polyester (Amid Type IV) and non-knitted, nonwoven mesh such as OBTAPE® and UraTape® (both Mentor–Porges, Le Plessis Robinson, France), have been documented to have a much higher incidence of erosion (16–25%) compared with that of type I meshes (0–10%).[105,109,124,301]

As described previously, bladder, urethral or vaginal perforation during the original surgery increases the risk of subsequent sling erosion by approximately 26-fold.[31] In addition, passage of the trocar through the vaginal, bladder or urethral wall without actually penetrating the lumen might occur, which would result in positioning of the mesh just barely under the surface of the lumen and predisposing it to erosion. This possibility seems likely, although it is currently unproven.

The approach to treatment of sling erosions has been largely empirical, follow-up durations of studies in this area have been short and only a few studies have applied validated outcome measures, especially with respect to the occurrence of other symptoms, such as lower urinary tract symptoms, pain and dyspareunia.[9,44] As discussed previously, recurrent SUI after mesh removal is not uncommon.[9,43,78,84,85,94,100,138] However, synchronous anti-incontinence surgery can be effective in this setting.[43] The authors of this study[40] based their decision to conduct synchronous autologous sling surgery on multiple factors: the location of the urethral injury; preoperative continence status; and the degree of urethral hypermobility. In our series,[9] the success rate (based on PGII score) was 82% after mesh removal, but only half of the patients underwent synchronous autologous sling surgery.[9]

Mesh erosion in the bladder

Bladder erosions are reported to occur in 0–15% of patients fitted with a SMUS (REFS 16–20,22,26,30,46–48,



◀ **Figure 2** | Identification and removal of eroded mesh. **a** | Eroded mesh can be difficult to see during cystoscopy owing to its almost translucent appearance in some patients. **b** | In this erosion, the sling is nearly obscured by the presence of calcium deposits. **c** | Appearance of eroded Amid Type I mesh at urethroscopy. This mesh had no appreciable tissue ingrowth and pulled out of the urethra easily, leaving a small urethrotomy that was closed with a few sutures. **d** | Surgical explantation of eroded silicone mesh. In this case, removing the mesh was relatively easy because it was an Amid type IV mesh, which was encapsulated. **e** | Transvesical explantation of an eroded mesh sling. This type I mesh had tissue ingrowth and required delicate surgery and sharp dissection to enable removal. **f** | Following sharp dissection, the mesh was completely excised from the bladder wall. It coursed over, but did not damage, the ureter. Permission obtained from Fred Govier and Kathleen Kobashi, Virginia Mason Hospital & Seattle Medical Center, Seattle, WA, USA.

50,52,53,55–73,75–77, 79,81,82,86–90,92,93,95–100, 140,152,155–160,164,166–168,170–172,174–177,181, 183–185,207–209,213,215,217–219,221,229,231,233, 234,245,247,253,254,257,258,260,265,266,288–293). Patients with mesh erosions in the bladder usually present with recurrent UTIs, haematuria, bladder stones, incontinence, dyspareunia and pelvic pain; mesh erosions are typically discovered during cystoscopic examinations (Figure 2). Most authors agree on the general treatment principle—all mesh must be removed from the bladder—but the procedures used to do so vary widely. A variety of endoscopic approaches have been used to remove mesh including cutting with scissors and removing the mesh with grasping forceps, transurethral resection of the mesh using monopolar or bipolar current, vaporizing it with a holmium laser[302–310] and even utilizing a small nasal speculum or Metzenbaum scissors passed transurethrally alongside a cystoscope.[311] Results achieved with these surgeries[300–309] have been variable, with some successes followed up for as long as a few years, but the majority of studies had short follow-up durations. Open surgery using a suprapubic or vaginal approach has the advantage of removing all of the intravesical mesh, including mesh that traverses the bladder wall (Figure 2).[9,43,312] Sometimes, partial cystectomy is necessary to remove all the intravesical mesh;[9,10,313] laparoscopic approaches have also been tried.[138] Unfortunately, few studies of patients with mesh erosions in the bladder have sufficiently long follow-up durations or good enough outcome measures to determine the true success rates of these surgeries. Furthermore, all reported successes and failures were compared to the patient's status before the mesh removal surgery, and not before SMUS implantation surgery.

Mesh erosions in the urethra

Urethral erosions are much less common than bladder erosions in patients fitted with a SMUS, with a reported incidence of 0–2.6%.[46,61,100,176] Urethral strictures caused by mesh erosions are even rarer than urethral erosions.[314] A number of different aetiologies of urethral erosion have been postulated, including surgical transgressions (excessive sling tension, unrecognized urethral perforation and passage of the sling through the urethral wall), urethral dilatation,[281] postoperative contraction of the sling,[315] infection, inflammation and immunological reactions.[33,315–319] Treatment of urethral erosions might be as simple as excision of the mesh, which sometimes pulls easily out of the urethra, (Figure 2) or can involve extensive surgical excision of the mesh with part of the urethral wall requiring urethral reconstruction and a Martius flap (Figure 3).[320]

Vaginal mesh erosion, extrusion or exposure

Vaginal mesh erosion, extrusion or exposure has been reported in 0–19% of patients with a SMUS (0–11% of patients with an RP sling and 0–19% of patients with a TOT sling, REFS 16–20,22,26,30,31,46,48,50,53,58–60, 62,64,65,67,69,70,72,75–77,79,81,82,86–90,92, 95,97,103,140,156,158,160,164,167,170,175,177,183, 185,218,221,231,233,247,257,260,266,288,291,292). Factors associated with a higher incidence of mesh extrusion include trocar perforation of the vaginal wall during mesh implantation, previous pelvic surgery, diabetes, bleeding complications at the time of surgery, pelvic radiation, smoking, older age and vaginal incision length >2 cm.[31,42,321]

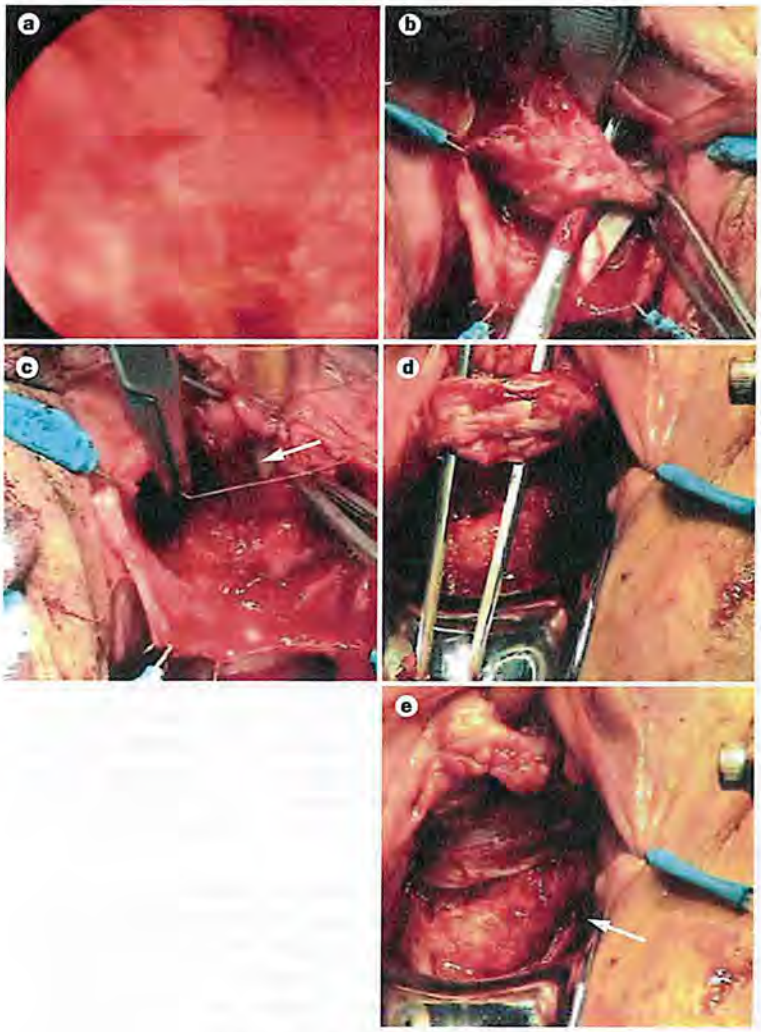


Figure 3 | Identification and removal of Amid type I eroded mesh surrounding the urethra. **a** | Urethroscopic view of urethral erosion. In this case the erosion was very subtle and located in the distal urethra, such erosions are very easy to miss. **b** | Transvaginal dissection and isolation of the mesh shown in image a reveals marked scarring and tissue ingrowth. **c** | Removal required sharp dissection that left a large defect in the urethra (arrow) that required urethral reconstruction, Martius flap and implantation of an autologous fascial sling. **d** | The sling being placed over the urethra. **e** | Creation of a Martius flap (arrow) between the reconstructed urethra and sling, thus repair is completed before vaginal wound closure.

We postulate, based on our clinical experience, several other causes of vaginal mesh exposure including wound dehiscences resulting in exposure of the mesh or implantation of the mesh superficial to the pubocervical fascia so that it lies just beneath the surface.[9] When conditions that favour mesh erosions in the vagina are compounded by local ischaemia, inflammation, foreign body reaction and/or infection, the risk of erosion is likely to be increased. An alternative causative factor has also been suggested —defective wound healing caused by an immunological response to the mesh itself.[33] Vaginal mesh extrusion frequently presents as dyspareunia, vaginal discharge, vaginal bleeding and pain experienced by the sexual partner during vaginal intercourse ("hispareunia").[322] Sometimes asymptomatic extrusions are found during a routine vaginal examination. A diagnosis of vaginal mesh extrusion is typically based on a physical examination —by visual inspection and/or palpation (Figure 4). Most vaginal mesh extrusions occur within the first year of SMUS implantation, although they have been observed in patients as long as 17 years after the original surgery.[16] Some authors report that small areas of mesh exposure can be successfully treated with topical oestrogen,[323] although the results have been mixed.[324] Larger mesh exposures require primary closure of the vaginal wall over the exposed mesh or surgical excision and closure with or without vaginal wall flaps.[30,41–43,45] Mesh exposures of this type are usually reported as minor complications; post-treatment follow up in these patients has been woefully inadequate in most studies.[319,323–325] We did not find sufficient justification in the literature to be able to confidently assess the long-term success of treating these minor exposures. For example, in a retrospective review of nearly 347 complications, the authors found that 73% of patients who initially had nonsurgical treatment for vaginal mesh extrusions ultimately required surgical treatment within 5 years of the original sling surgery.[16,44] In a single-institution study of 79 patients who underwent SMUS implantation, the mean time from SMUS implantation to removal was 2 years with a range of 0–11 years. Despite the fact that mesh erosions can occur >10 years after implantation, most studies report a mean follow-up duration of only 2–23 months.[16,105,261,277,301,312,326]

Mesh erosions in the bowel

Bowel mesh erosions are exceedingly rare and all known patients with bowel erosions have presented with an enterovaginal fistula.[9,327,328] Treatment requires removal of all intra-abdominal mesh and repair or excision of the affected bowel. In our own clinical experience, a patient who had bowel mesh erosion had an associated vesicovaginal fistula and after several unsuccessful reconstructive surgeries required a continent urinary diversion.[9]

Pain

Pain is the most poorly studied complication of SMUS surgery; we found only a few studies that included prospective data collection and/or validated questionnaires assessing pain.[30,79,90,95,152,168,174,229,254] Some investigators used postoperative questionnaires that contained pain questions, but most relied on patients' recall or chart review.[39] In addition, many different descriptors of pain have been reported including vaginal, pelvic, groin, thigh, leg, suprapubic and lower abdominal pain, dyspareunia and "pain, patient self-report."[30] Two different kinds of pain caused by nerve injury have been suggested: centrally mediated hyperalgesia and a peripherally mediated painful hypoalgesia, suggesting the need for mechanism-based classification of neuropathic pain.[329] Most importantly, few of the case studies of patients with SMUS-related pain quantified the severity of this pain,

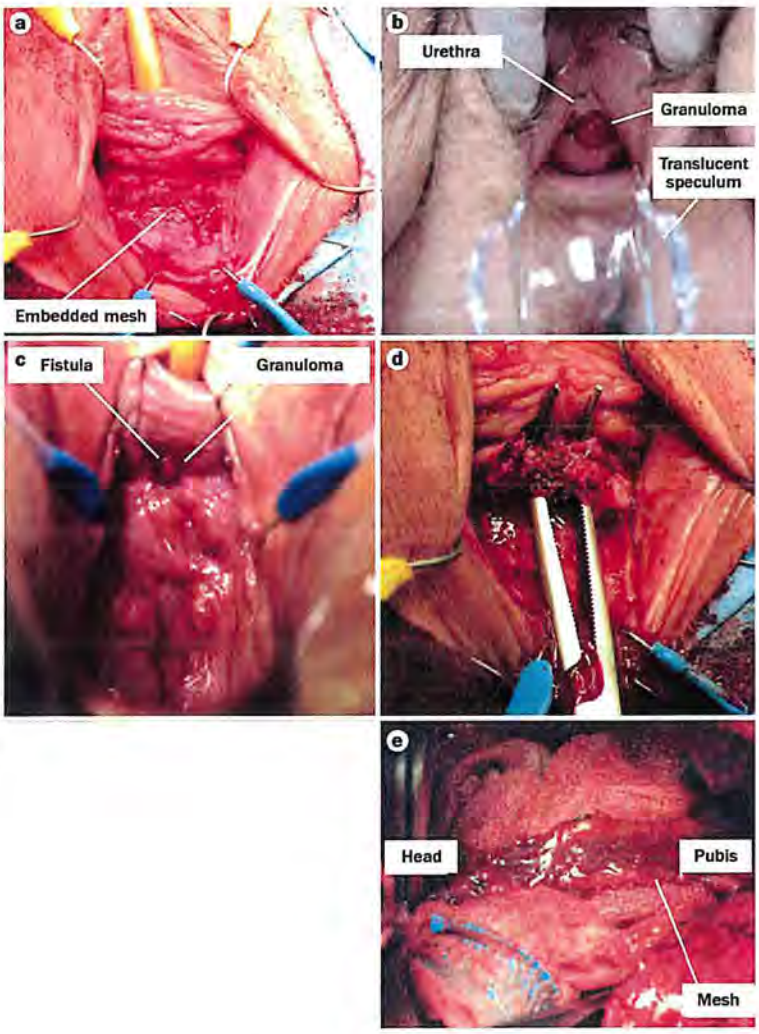


Figure 4 | Vaginal complications and removal of SMUS. **a** | View of mesh extrusion into the vagina. This extrusion was both readily visible and appeared palpable on physical examination. **b** | Transvaginal view of eroded mesh obscured by a granuloma. The erosion was neither visible nor palpable. **c** | Transvaginal view of fistula obscured by granuloma. **d** | Transvaginal explantation of an Amid type I RP sling. Note the dense tissue ingrowth and scar that requires sharp dissection in order remove the suburethral portion in its entirety. This portion of the sling felt thickened and stiff. **e** | Retropubic view in the same patient, as shown in image d. The retropubic portion of the mesh after dissection showed fatty tissue ingrowth. This portion was pliable and not scarred. Abbreviations: RP, retropubic; SMUS, synthetic mid-urethral sling.

its character or how the pain affected patients' quality of life.[30,64,82,263] This neglected topic is of the utmost importance and permanently affects "a small cohort of patients whose lives have been unalterably changed for the worse."[40,312]

Pain in patients with a SMUS has been attributed to direct nerve injury during implantation, nerve entrapment, haematoma, infection, chronic inflammation, structural changes to the implanted mesh (shrinkage, stiffening, hardening and/or banding) and scarring.[38,330] Most patients present with pain within the first year of surgery, although some present years later—as late as 8 years postoperatively.[9,110,143] In studies of effectiveness and safety, pain was mostly divided into perioperative pain and pain lasting more than 6 weeks. Perioperative pain has been reported in up to 33% of patients,[252] occurring more frequently after implantation of TOT slings than RP slings,[331] and chronic pain (of any definition) has been reported in 0–31% of patients (REFS 17,18,20,30,39,47,48,53,58,59,61–63,66,69,70,73,76,79,82,89–91,95,98,99,140,152,155,159,164,167,168,171–174,177,180–182,185,208,209,215,223,229,231–233,235,247,250,252,254,255,257,266,268,290,332,333).

Chronic disabling pain is one of the most common indications for mesh removal, particularly in patients fitted with TOT slings.[9,38,42,44,110,111,277,326] Chronic pelvic pain often contributes to a need for mesh removal; however, these data might not be captured by the approaches used by all investigators. Thus, the reported incidence of pain complications is likely to be falsely low. In comparison with patients with an RP sling, patients with a TOT sling have a higher incidence of persistent pain (32% versus 10%) and dyspareunia (18% versus 3%).[116] This finding is confirmed by a review and meta-analysis in which the rates of chronic groin and leg pain were higher in patients with a TOT sling compared with those of patients with an RP sling (16% versus 6.5%, respectively).[206]

Treatment of persistent pain in patients with a SMUS is particularly challenging and has been entirely empirical and progressive in nature. The treatment approach in these patients typically begins with pain medications and neuromodulatory medications such as carbamazepine, physical therapy or trigger-point injections and culminates with partial or complete mesh excision. Reported success rates of these treatments range from 24% to 100%,[9,40,43,107,277,312,326] but use of validated outcome measures documenting treatment success and long-term follow-up monitoring are both lacking. Furthermore, a number of case studies and series of patients with mesh complications have commented on the lifestyle-altering nature of painful complications in these patients.[9,40,107,312,326]

Fistulas

Urethrovaginal and vesicovaginal fistulas are rare SMUS-related complications, with a reported incidence of <1%.[46,48,66,98,173,178,212,217,334] These fistulas are most frequently associated with bladder or urethral erosion of the sling and patients can present in a variety of ways, and as late as 6 years after the initial surgery.[41,43,44,335–338] Despite their low reported incidence, the possibility of fistulas should be considered when patients present with recurrent incontinence, OAB, pain and/or voiding dysfunction after mesh surgery.[41] Not infrequently, a diagnosis of fistula can be obscured, owing to the presence of adjacent granulation tissue (Figure 4). Concurrent sphincteric incontinence might also confound diagnoses of fistulas,

especially in patients with a urethrovaginal fistula; thus, a careful evaluation should be undertaken to exclude fistula whenever a patient has recurrent incontinence after mesh sling surgery. This evaluation should include a physical examination with a stress test and visual confirmation that leakage is occurring through the urethral meatus as well as cystourethroscopy.[41] Surgical repair of urethral or vesicovaginal fistula requires the complete removal of all involved mesh and possible vaginal reconstruction with tissue flaps.[339] In patients with concomitant sphincteric incontinence, synchronous repair of a urethrovaginal fistula and an autologous fascial sling with a Martius flap interposed between the fistula repair and sling is often an effective treatment.[41,43]

Death

Mortality is the least common SMUS-related complication. In fact, in our literature review we did not find a single case series report that contains a postoperative death of a patient undergoing SMUS implantation surgery; However, In a study of bowel complications of SMUS, published in 2007,[133] 7 deaths from bowel injuries after RP sling implantation were reported, and in 2014 another death after bowel perforation during a retropubic SMUS implantation was published as a case report.[132] Authors of a review of database entries regarding SMUS complications reported 10 deaths owing to bowel injury (six), vascular injury (three) and sepsis (one).[10] Authors of this study[10] suggested that death is an under-reported complication in patients treated with a SMUS.

Complications from mesh removal

Published reports on long-term outcomes of patients after mesh removal surgery are limited. All published studies are retrospective chart or database reviews and substantial heterogeneity exists in terms of both methodology and outcome measures.[9,41,43,44] Most authors of studies in this area commented on the technical difficulties encountered during mesh excision surgery and the fact that many (in some series, most) patients require two or more surgeries; thus, even in the short term, outcomes are often suboptimal.[6,9,40–45] Patients who underwent surgery with a primary indication of urethral obstruction had the highest success rates and those whose primary indication was pain had the least successful outcomes. Perioperative decision making is difficult in these patients and is often highly individualized, mostly based on the surgeon's experience and preferences: whether to attempt removal of all the mesh or just the suburethral or vaginal portions and whether to use a synchronous anti-incontinence or urethral reconstruction procedure.[9] Of note, in patients requiring mesh removal, recurrence of SUI has been reported in 10–60% of individuals.[9,43,78,84,85,94,100,138] An understanding of the possible outcomes of salvage surgery for mesh complications is critical in enabling accurate decisions regarding informed consent for the use of primary mesh surgery; however, few prospective or registry-based studies with published results currently exist that might address this need.[9,44,326]

Mesh–body Interactions

Despite the extensive use of polypropylene mesh dating back to the late 1950s,[340] in a variety of medical procedures, a paucity of data currently exists regarding the fate of this type of mesh once implanted in humans. Almost all of our knowledge of mesh–body interactions is derived from animal studies; explanted material from patients has been largely neglected as a source of information in this area. After >50 years of use, only a few published studies exist in which investigators actually examined histological changes in mesh explants that had been removed from humans.[35,341–343]

Despite this general lack of information, in one study of human explanted mesh samples and pathology records from 102 patients, <50% of explanted transvaginal mesh specimens were examined microscopically; however, when microscopy was performed, results of the microscopic examinations usually did not explain the specific complications experienced by the patients.[253] Several studies have confirmed this finding, noting that the assumption that mesh is widely considered to be biologically inert is based on results of short-term animal experiments without corroborating studies in humans.[342–344] At present, general human tissue interactions with the mesh are known, but we have an incomplete understanding of interactions specific to a mesh material and design as well as the pathophysiology of any complications.

Tissue responses to mesh

Inflammatory reactions

The inflammatory response to implanted mesh is nonspecific, similar to the foreign-body type of reaction initially described in the late 19th century.[345,346] However, only since the 1990s have tissue–implant interactions been studied, and, to date, few reports of the mechanisms involved have been published.[342–344] Immediately after implantation, foreign bodies, including modern implantable polymers, become coated with proteins followed by the appearance of inflammatory cells that migrate into the tissue, owing to the action of inflammatory mediators.[347,348] As in any tissue injury, the acute phase of inflammation is characterized by the appearance of short-lived neutrophils. Neutrophils are replaced within days by macrophages, which persist indefinitely. The initial phagocyte migration towards the foreign body does not seem to be driven by chemoattractants, but is dependent on the proteins, specifically fibrinogen, coating the implanted objects.[347,348] The macrophages then either persist and take on an epithelioid appearance or fuse to form multinucleated giant cells. Macrophage fusion occurs in the presence of certain cytokines, when the foreign object is too large to be phagocytosed by a single cell.[349] The macrophages are recruited in an attempt to destroy the foreign object and are the main component of the granulomatous inflammation triggered by the foreign body. The macrophages secrete an array of substances, such as bioactive lipids, hydrolytic enzymes, reactive oxygen metabolites and mediators of fibroblast proliferation.[350,351] In addition to

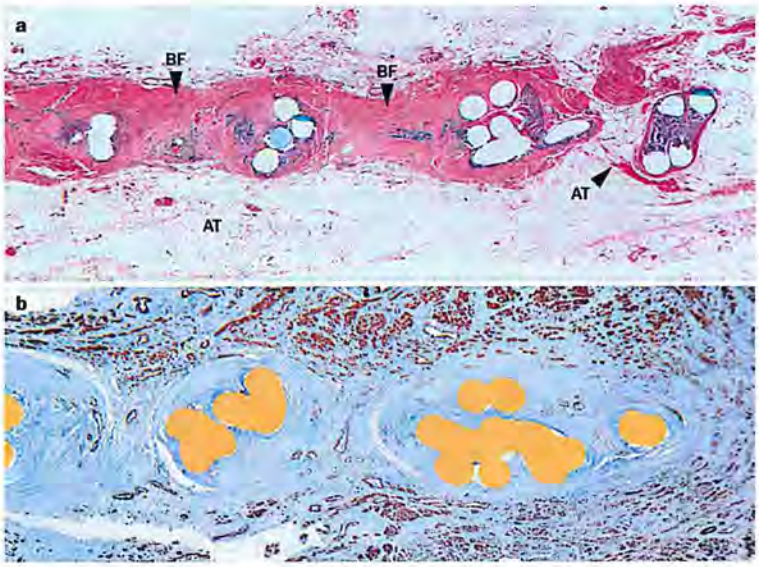


Figure 5 | Scar encapsulating mesh and surrounding pre-existent normal adipose and muscular tissues. **a** | ×2.5 image of a histological section showing a cross-section of mesh filaments as they appear in section, without colouring. Some filaments were labelled blue by the manufacturer. Adipose tissue had been present in the area before mesh placement. Tissue reaction to surgical injury and the mesh generated scar tissue encapsulating the mesh appears as dense pink collagenous tissue. The scar spans, or bridges, across mesh pores, which is termed bridging fibrosis. In this case a terminal pore contains nonscar adipose tissue (arrow with AT). This section has been labelled with a haematoxylin and eosin stain. **b** | ×2.5 image of a histological section showing cross-sections of mesh filaments. Note that the mesh is surrounded by a halo of fibrous tissue separating it from the pre-existent tissue of the vaginal wall, containing smooth muscle. Smooth muscle is labelled with anti α smooth muscle actin (brown), mesh filaments are filled yellow. The blue colour is a haematoxylin background stain. Abbreviations: AT, adipose tissue; BF, bridging fibrosis.

macrophage-mediated effects, a granulomatous reaction includes T lymphocytes as well as a smaller proportion of B lymphocytes and plasma cells. Each mesh filament ultimately becomes surrounded by a sheath of granulomatous inflammation and the entire mesh structure remains chronically inflamed.[342,352–354] Three clinically important aspects of mesh-induced inflammation exist: inflammatory mechanisms of pain, stimulation of fibrosis and polypropylene degradation.

Mesh integration

Mesh integration into the tissue is the result of wound repair mechanisms, which aim to restore tissue continuity. In most mammals after the foetal stage of development, the damaged tissue and void spaces are filled with fibrous, or scar tissue. This fibrous tissue functions as a nonspecific universal repair material or filler. In relation to implanted mesh, the body needs to repair tissue that was damaged during surgery, as well as fill the spaces within the mesh structure. The body also needs to repair the tissue damaged by mesh-associated inflammation.

With implanted mesh, granulomatous tissue inhabits the spaces within the mesh structure, such as the pores and interstices between mesh filaments; however, only provided the spaces are large enough to allow tissue ingrowth.[344] During the weeks after SMUS implantation, collagen deposits accumulate, while the fibroblasts acquire contractile filaments and transform into myofibroblasts. The contractile functions of these myofibroblasts together with reduction of extracellular fluid and collagen crosslinking results in wound contraction;[316,355] the overall aim of wound contraction being to minimize the volume of the maturing scar. In the scar-inhabiting mesh, the contractile forces act on the interlocked mesh–scar composite structure, which results in mesh contraction.[103,316,356] Maturation of the newly generated fibrous tissue is the next step in the repair process. During this maturation stage, collagen becomes increasingly organized and the density of the microvasculature recedes.[355]

Initially, the scar is composed of type III collagen, which is replaced by type I collagen as the scar matures. In the transition from type III to type I collagen, the structure is rearranged into cross-linked sheets that run parallel to tension forces.[355] The repaired area becomes a hypocellular scar that is then slowly remodeled, which can take ≥1 year to complete. Repeated or continuous damage to the tissue can cause the process of repair to be renewed at any stage. Thus, chronic inflammatory conditions can generate a large amount of scar tissue.

With foreign bodies such as mesh, the repair process is complicated by the inflammatory reaction, which is a stimulus for fibrosis. The amount of scar tissue that accumulates is dependent upon counterbalancing processes: stimulation, owing to the presence of a foreign body, and reduction of the scar volume by remodeling. In relation to implanted meshes, fibrous tissue fills the spaces within the mesh structure and surrounds the mesh.[342,343] The tissue then undergoes contraction and remodeling: the stimulus for fibrosis is, therefore, stronger around the mesh filaments and weaker far from the filaments, that is, in the mesh pores. Some larger pores might include fat or other components of normal connective tissue, while the surrounding filaments are fully encapsulated by the scar (Figure 4).[35] Bridging fibrosis can occur in the mesh, where the scar spans or bridges across the pores (Figure 5). Lightweight mesh designs containing pores of several millimetres in diameter have a greater chance of containing normal, nonscar connective tissue in the larger pores of their complex structures.[35,343] By contrast, heavyweight mesh designs, which are currently used for SMUS devices, lead to the development of a continuous scar plate, which encases all mesh filaments and spans across most of the pores (Figure 5).[35,343,357] Scar tissue also provides a connection between the composite mesh–scar structure and the surrounding normal tissue.

The process of healing also includes restoration of interrupted innervation and innervation of newly formed tissue. After mesh implantation the processes of reinnervation and/or neoinnervation are not overly affected by the presence of mesh.[34] Results of a study published in 2014, investigating samples from patients with inguinal hernia showed that the density of nerve branches in the scar encasing the mesh is similar to that of normal tissue

before surgery and marginally, but not significantly, lower than in the scar formed after non-mesh surgery.[34] In addition, nerve branches were observed in the interstices and pores of the mesh, probably growing through the mesh similar to small vessels that were observed to cross the mesh plane.[34] This finding indicates that tissues superficial to the mesh might be at least partially dependent on the through-the-mesh neurovascular supply (Figure 6).

Mesh degradation

The authors of several studies have reported degradation of polypropylene in explanted meshes;[36,341,358–361] however, the question of whether polypropylene degrades *in vivo* has not been fully resolved, despite decades of use.[37,362] Most conclusions of studies in this area were based on the observations of cracking on the exposed surfaces of explanted mesh filaments, which are usually examined using scanning electron microscopy.[351–353,355] The explanted tissue examined in these studies was typically fixed in formalin and had to be separated from the mesh using chemical reagents. Alternative hypotheses emerged that the cracking was either of residual biofilms or, if degradation occurred, it was induced by the formalin or cleaning reagents used. However, other studies demonstrated a similar appearance of polypropylene degradation occurring outside of the human body.[363–365] Before the publication of scanning electron microscopy studies of the mesh surface, authors of an earlier study, published in 1976, assessed the mechanical properties and molecular weight of implanted mesh and concluded that polypropylene degrades *in vivo*.[366] In this study, the investigators placed polypropylene implants with and without antioxidant subcutaneously in hamsters to determine the rate of degradation of the implant. They periodically removed specimens during a 5-month test period and analyzed the samples using infrared spectroscopy and dynamic mechanical testing.[363] The analyses showed that degradation began to occur after only a few days, although several factors suggested that the *in vivo* degradation process was similar to autoxidation that occurs in air or oxygen; in this study, the oxidation process was retarded through the use of an antioxidant.[363] A lack of published studies exists in this area, although the limited evidence suggests that implanted polypropylene undergoes a process of oxidative degradation, in which one of the factors is believed to be oxidative substances generated by macrophages.[366,367]

Effects of mesh on the tissue

Pain

Scar tissue inhabiting the mesh is not simply an inanimate filler, but a living tissue with its own vascular supply, innervation, fluid and acid–base balance mechanisms and immune response.[34,253,368] This tissue is subject to pain through normal mechanisms, caused by specific factors: persistent chronic inflammation, nerve ingrowth, tissue compartmentalization within the mesh and nonphysiological attachments to mobile tissues.

Inflammatory mediators cause hypersensitivity to everyday stimuli that leads to pain in response to touch or on movement and, if the stimulus is sufficiently high, can even lead to pain sensations at rest.[369] As discussed earlier, implantation of polypropylene meshes invariably results in an inflammatory response, which creates an environment capable of decreasing a patient's pain threshold (Figure 7).

The interlocking and compartmentalized nature is another specific feature of the mesh–scar complex. The ingrown tissue is in a vulnerable position, as it might be subjected to physical compression and distortion within the compartments of mesh pores and folds.[34] The risk of

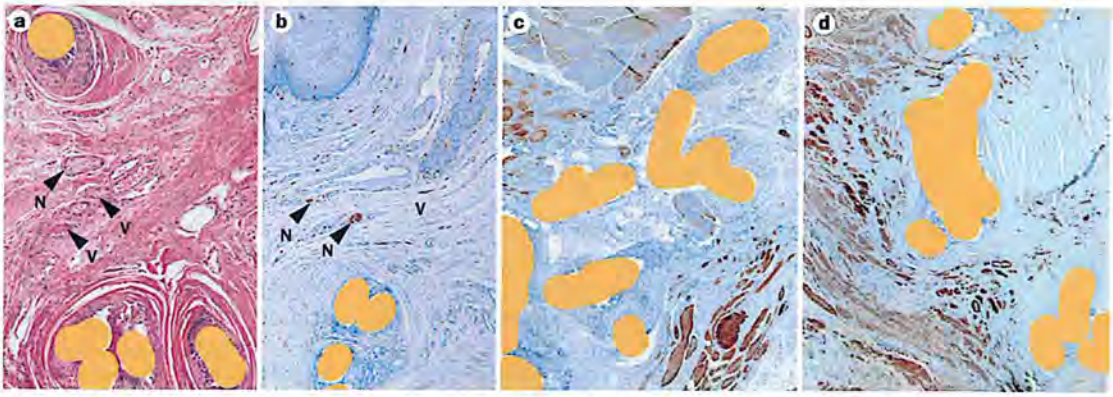


Figure 6 | Tissue interactions with explanted sling materials. **a**,**b** | ×10 images of a histological section showing a neurovascular bundle penetrating through a mesh pore. This section has been labelled with a haematoxylin and eosin stain. Cross sections of mesh filaments are filled yellow for demonstration purposes. The neurovascular bundle is within a mesh pore, orientated perpendicular to the mesh plane. **c** | ×10 image of a histological section showing muscle interposition between mesh filaments. This section has been anti-desmin-labelled (brown) to highlight the presence of striated muscle. Interlocked striated muscle is commonly observed in explanted transobturator tapes. **d** | ×10 image of a histological section showing α-smooth-muscle-actin-labelled smooth muscle from the vaginal wall, urethra or urinary bladder surrounding the sling material. Depending on the muscle origin, smooth muscle is likely to interact with mesh during physiological contractions (such as those that occur during urination or intercourse). Abbreviations: N, nerve branch; V, blood vessel.

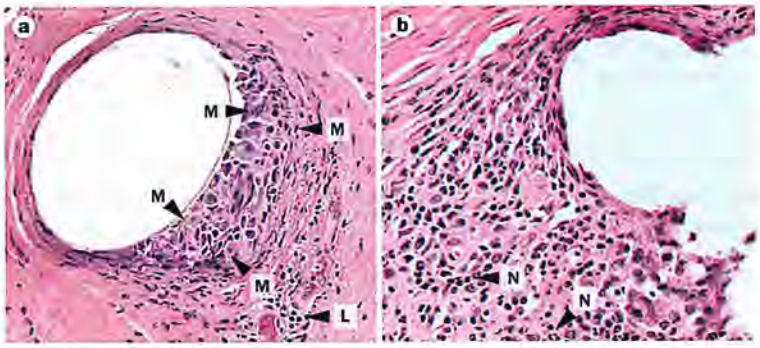


Figure 7 | Inflammatory reaction to the mesh. **a** | ×40 image of a histological section showing a cross-section of mesh filaments surrounded by foreign-body-type inflammation. Epithelioid macrophages (between arrows 'M'), which are the main component of granulomatous inflammation can be observed. A smaller number of lymphocytes ('L') can be seen seen surrounding the mesh filament. This section has been labelled with a haematoxylin and eosin stain. **b** | ×40 image of a histological section showing a cross-section of mesh filaments, characterized by the presence of neutrophils (multiple neutrophils are scattered in the infiltrate, two are labelled 'N' as examples). Acute inflammation is a feature of bacterial infection and is seen in patients with mesh exposure through the vaginal, urethral or bladder mucosa. Abbreviations: L, lymphocytes; M, macrophages; N, neutrophils.

compression might be a result of external forces, such as moving, bending and penile thrusting during intercourse, as well as a result of increased interstitial fluid pressure within the compartments. We have observed evidence of oedema within pores and deformation pockets (folds) of larger mesh devices indicating fluid imbalance within the mesh compartments (Figure 8). Externally, scar connection to the surrounding tissue might cause distortion and pulling during movement. These forces can act on the entire mesh structure, which in a SMUS has a long course compared with that of a hernia patch. This relatively long length of a SMUS might result in multiple sites of scar attachment to the tissues, which, in the case of TOT slings, includes actively contracting striated muscle.[277] These nonphysiological connections are subject to pulling forces that might induce pain, either as a result of muscle contraction or mobility during body movements. Additionally, mesh shrinkage during scar contraction might lead to static tension within and between attached tissues, also contributing to pain.[103]

Many authors have suggested nerve entrapment as a cause of SMUS-related pain. Entrapped nerves have been detected in mesh explants from patients with hernia,[34,35,370] and nerve branches have also been shown to grow into the mesh interstices in up to 90% of explanted mesh samples from patients with hernia.[34,35] Nerve entrapment has also been reported in patients fitted with a transvaginal mesh,[112] although few published studies exist in this area. In our unreported clinical experience of over 100 explanted mesh specimens, nearly all contained nerve branches of variable calibre (Figure 6). Interestingly, in patients undergoing hernia surgery, prophylactic neurectomy is offered as a method to reduce the incidence of pain after mesh repair.[371]

Some patients fitted with a SMUS report pain that is associated with specific movements or activities. The observation of interlocking of the mesh and striated muscle—resulting in muscle contraction and traction on entrapped nerves—offers a plausible hypothesis to explain this phenomenon in patients fitted with TOT slings. We have also observed interposition of smooth muscle, which might contribute to dyspareunia as the vaginal walls contract during intercourse (Figure 6).

Dyspareunia

Direct pressure and a wide range of tissue movement during sexual intercourse both pose additional risks to patients with a SMUS. The vaginal mucosa is one of the most densely innervated parts of the human body. Thus, if this mucosa overlies a stiffened mesh–scar structure, the nerve branches and receptors are subject to compression against the stiffened SMUS during intercourse. In addition, tissue movement on either side of the scar plate can cause traction and distortion of the mesh–scar structure. Findings of a study published in 2010[38] demonstrated the existence of a new complication unique to patients fitted with TOT slings, termed banding, which is a palpable firm scar in the paraurethral folds that was associated with dyspareunia in four of 12 sexually active women who were found to have banding on examination. Unfortunately, no data were presented describing the histopathology of excised tissue that was removed owing to painful banding, although little imagination is required to understand how this effect could cause pain (Figure 9).

Mesh exposure in the vaginal wall

Mesh erosion through the vaginal mucosa can result in a large variety of tissue responses, ranging from no detectable changes to substantial acute inflammation (Figure 7) and even formation of small abscesses. The dense acute inflammation almost always signifies bacterial infection.[372] From our unpublished experience, the site of mesh exposure also has a variable amount of granulated tissue. These changes correlate with the presenting symptoms, which range from no complaints to vaginal discharge, bleeding, dyspareunia and feeling of the exposed edge of the mesh by the sexual partner.

The mechanisms of mesh exposure and/or extrusion through the vaginal wall have not been well studied; however, an approximately 26-fold increase in vaginal and bladder exposure, extrusion or erosion when there had been a vaginal or bladder trocar perforation during the original surgery is known to exist.[31] Other risk factors have also been identified including patients' having undergone prior vaginal surgeries, larger incisions, smoking, diabetes mellitus of either type, pelvic exposure to radiation and older patient age.[96,124,321] The existence of these risk factors suggests that poor healing, lowered antibacterial immunity, insufficient vascularization, and scarring are all possible causes contributing to mesh exposure. In terms of mesh-specific factors, solid silicone strips or silicone-coated meshes have higher rates of erosion, indicating that choice of material

can affect the risk of vaginal mesh exposure.[105,373,374] Compared with other SMUS materials, silicone has limited adhesion to the tissues, which possibly enables more movement of the mesh, or tissue detachment. Patients fitted with a SMUS with a design that incorporates microporous materials with low tissue adherence, such as Gore-Tex® also have higher rates of mesh exposure through the vaginal wall,[375] compared with those of patients fitted with a SMUS that incorporates polypropylene mesh, which has larger pores.[301,356,376] In addition to the lower tissue adherence that enables mesh movement within the tissue, meshes with smaller pores do not allow tissue growth through the mesh. This lack of tissue growth likely interferes with vascularization and innervation of the overlying mucosa, which might lead to dystrophic changes and poor resistance to infection and necrosis.

Results of experiments conducted in animal models showed that the rate of mesh erosion was also dependent on the size of mesh implant, with animals implanted with larger mesh patches having a higher risk of exposure.[356,376] The higher exposure rate of larger mesh implants was likely a result of higher risks of mesh migration. Deformation was associated with the use of larger patches, more interference with vascularization and innervation of the overlying mucosa and the presence of larger volume of inflammation and/or fibrosis. Implantation with a smaller area of mesh might result in less risk of exposure, assuming that exposure is an entirely random event. In our unreported clinical experience of over 100 explanted polypropylene slings, we frequently observed that the exposed part of the explanted mesh was a curled edge piercing through the mucosa, suggesting that edge curling is also a mechanism of vaginal mesh exposure. In addition to the internal properties of a knitted structure, outward pressure of the tissue can act to curl the edge. Interestingly, resection of an exposed part of the mesh, either an edge or a mid-portion, leaves new edges that can also curl and become exposed. In our experience many mesh exposures, SMUS-related or implant-related pelvic organ prolapses recur after trimming of the exposed part.

Mesh migration

Mesh exposure through the vaginal wall seems to have several potential causes. Mesh erosion through the urethral or bladder mucosa reflects mesh migration (or incorrect SMUS placement). Mesh migration through the tissues and into the adjacent organs has been described when used in patients with hernia, in which two types of mesh migration have been suggested to occur: primary migration of unsecured mesh towards areas of least tissue resistance and secondary migration through transanatomical planes. The latter is facilitated by tissue forces acting to displace mesh while remodelling-induced and inflammation-induced tissue resorption enable this movement.[377,378] In patients with SMUS, mesh migration typically occurs into or through the urethral wall, which is a secondary type of migration.[9,10,39,41,326] Excessive tensioning of the sling can act to displace the mesh into the urethra, whereas an inflammatory reaction to a foreign body and the general ability of tissues to remodel under chronic pressures can enable mesh migration. Remnants of partially excised SMUS can potentially migrate in directions other than into the urethra.

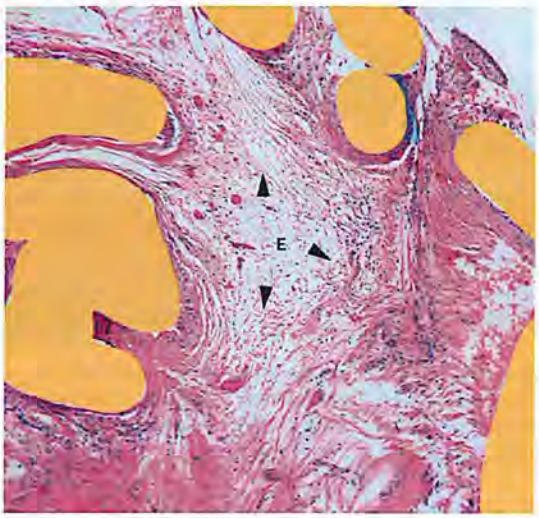


Figure 8 | Oedema within mesh compartments. ×20 image of a histological section showing ooedema in mesh compartments, note separation of collagen and low density of tissue in the area of the oedema (E). Oedema is usually seen in semi-enclosed mesh compartments. Mesh filaments are filled yellow in this image. This section has been labelled with a haematoxylin and eosin stain. Abbreviation: E, oedema

Mesh deformation

Mesh deformation, in which a part of mesh moves from its original or intended position, is related to mesh migration. In an *in vivo* study using white rabbits, Amid type I (Marlex®) meshes were found to be more likely to fold or curl at the edges in comparison to Amid type II meshes (Teflon®).[379] Similar to mesh migration, deformation can be primary, as a result of intraoperative or perioperative folding and edge curling of an unsecured mesh, or secondary, occurring after tissue ingrowth. Secondary wrinkling and folding of the mesh is attributed largely to mesh–scar contraction.[316] For transvaginal applications, folding and bunching of the mesh is frequently observed in patients with pelvic organ prolapse, who are often fitted with large devices, whereas mesh deformation of SMUS devices is typically limited to edge curling (Figure 9).[380] Edge curling of knitted mesh materials has been noticed following their surgical use in patients with hernia, where the edges can be secured by stitching; however, transvaginal devices have all edges unsecured. Narrow sling tapes might also show signs of fraying and curling of the edges when stretched. To address this risk of sling deformation, SMUS manufacturers have used heat treatment approaches, with variable degree of success.[381] As we note, rotation of a frayed edge towards the mucosa is another possible

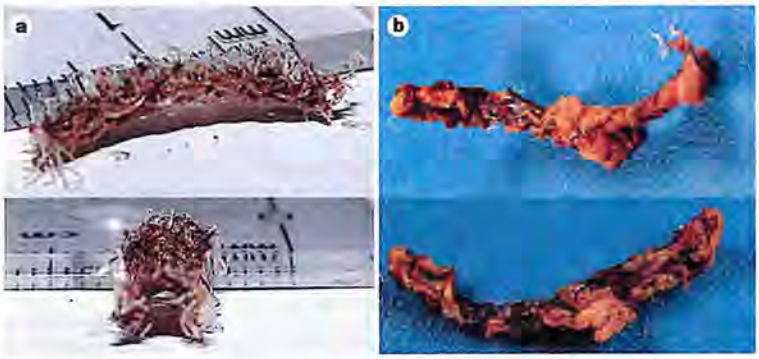


Figure 9 | Curling of the edges of explanted sling materials. **a** | Segment of a sling, which was explanted with very little adherent tissue and a structure that is readily visible. **b** | Segment of a mesh sling, which was excised with adherent tissue remaining attached to the sling material.

mechanism by which mucosal exposure of the mesh might take place.

Mesh stiffening

Elasticity and flexibility of knitted meshes is dependent on bending and movement of the mesh filaments. The extent of freedom of movement is often substantially reduced by the ingrowth of collagenous scar tissue. At the same time, the embedded mesh acts to reinforce the scar tissue, thus limiting native flexibility of the scar.[380,382–384] The resultant mesh–scar composite structure is stiffer than the original new mesh. The extent of the resultant increase in stiffness is dependent on mesh design, including the physical characteristics of the material and the amount of induced fibrous scar.[294,316,382–384] For SMUS devices, excessive tightening and connection to the surrounding tissues might limit mobility and add to the structural stiffness. This phenomenon has been observed in the clinic, where it is referred to as 'banding'.[38] Mesh stiffening is likely to occur owing to degradation of polypropylene, as the degraded layer often shows embrittlement.[357–359,361,366] This component of stiffening is expected to increase over time.

Urinary symptoms

SMUS are designed to support the urethra; however, as discussed previously, the amount of pressure can become excessive owing to mesh contraction and reduction of the area of support. A stretched mesh has a reduced width, which, together with edge curling has been described as 'roping' (Figure 9).[385] A stiffened, over-tightened sling, therefore, has limited elasticity and cannot accommodate a full range of changes in tension. SMUS tension changes dynamically during cough, sexual intercourse and other physiological processes, which adds to the static pressure on the urethra. The result is urinary retention and transmigration of the mesh into, or through the urethral wall. Interestingly, mesh removal does not necessarily lead to recurrent SUI.[369,370] This finding suggests that scarring around the mesh, which remains after mesh explantation, is sufficient to maintain continence in some patients.

Polypropylene degradation products

The breakdown of mesh is expected to result in the presence of small molecular complexes and chemical products of degradation, as is the case for any polymerized hydrocarbon. *In vitro* thermal degradation of polypropylene at high temperatures produces an array of organic molecules such as acids, ketones, ethers, aldehydes, alcohols and smaller hydrocarbons.[386] The *in vitro* conditions required for thermal degradation, however, are different to those observed under *in vivo* conditions, and we are not aware of any studies that either simulated body conditions or conducted chemical analysis of explanted tissue. An assumption can be made that, to some extent, any combination of the degradation products detected during thermal or other types of degradation can be produced in the tissue. Additionally, additives used to stabilize the polymer might theoretically leach into the surrounding tissue.

Accumulations of polypropylene degradation products are expected to be confined within the scar capsule and have more local, rather than systemic, effects on the body, owing to their fibrous encapsulation; however, no published studies currently address this point. The degradation products might act as an additional stimulus for the chronic inflammatory response. Accumulation and toxicity of these degradation products might cause tissue damage and contribute to the continuous remodelling around the mesh filaments and extension of fibrosis.[387]

Tumorigenicity

Three cases of cancer that might be associated with implanted polypropylene mesh have been reported in humans. Two patients had squamous cell cancers 6 years and 22 years after mesh hernia repairs, respectively;[388] in addition, an inflammatory myofibroblastic tumour following implantation of an RP sling has also been reported.[384] In the patients who had mesh hernia repairs, both had a complicated clinical course involving chronic mesh exposure and infection.[383] Chronic skin wounds are an established risk factor for squamous cell carcinoma. The one known patient with an RP-sling-related tumour had a myofibroblastic neoplasm with local recurrence potential, which is considered an intermediate state between a benign tumour and sarcoma. Potential risks of tumorigenesis in patients with SMUS include chronic mucosal erosions, chronic inflammation surrounding the mesh and the possible presence of degradation products and polypropylene additives released into the tissue. Mutagenic effects, in general can take many years to accumulate and then a long period to cause a neoplasm. Detecting any oncogenic effects of SMUS implants would require a large cohort of patients with the same type of implant, and these patients would have to be followed up for a sufficiently long period of time, most likely at least 15 years. The long-term use of hernia meshes has not revealed a significant oncogenic risk; however, the constant introduction of new mesh designs further complicates investigations of mesh-related cancer risks, as these new

designs probably vary in terms of the chemical composition of the polypropylene used. In general, based on our knowledge of tumorigenesis, three tissue types might be affected by introduction of a SMUS: epithelium; soft tissue; and lymphocytes, which could result in malignant transformation into carcinoma, sarcoma and lymphoma, respectively.

As described, a small risk of developing squamous cell carcinoma associated with chronic mesh exposure has been reported in patients with hernia meshes.[388] In transvaginal applications of similar materials, chronic erosions might, therefore, increase the risk of squamous cell carcinoma. The importance of concurrent local infections with high-risk variants of human papillomavirus needs to be studied, as these might have a synergistic effect in increasing a patient's cancer risk.

Carcinogenic effects of polypropylene, specifically leading to the development of sarcomas, have been studied in animal models. In rodents, implantation with flat polypropylene plates resulted in higher tumorigenicity than placement of porous materials.[389] A study of implanted polypropylene meshes in mice concluded that the risk of carcinogenesis following mesh implantation, if existent, is not immediate; however the follow-up duration of this study was only 2 years.[390] Another group of researchers implanted transponders made of polypropylene into carcinogen-sensitive *p53*$^{\pm}$ transgenic mice and observed development of sarcomas in 10% of animals within 6 months of exposure.[391] Other reports have corroborated these findings.[392–394] The basic research and clinical data suggest that implantation of polypropylene mesh might increase the risk of sarcoma, however if a risk is present in humans it is likely to be very low.

A potential risk of lymphoma needs to be considered in patients with any prosthetic implants, including SMUS, as this effect has been well documented in women with breast implants.[395,396] The exact aetiology of lymphoma owing to breast implants is not presently known, and this increased risk was detected in association with either saline or silicone implants. The increased risk of lymphoma might be related to an inflammatory reaction to the implants, rather than to the material of the devices; therefore, this risk might also be relevant to a large range of other implants that induce inflammatory responses, including SMUS. The large size of breast implants relative to most other implanted materials and the high volume of use for over 30 years might explain why this small, specific risk became detectable. Whether or not the same risk exists in patients with SMUS is currently unknown. In women with breast implants, the average time between implantation and a diagnosis of lymphoma is reported to be 9 years (range 1–32 years).[396]

Conclusion

In the words of the astronomer Carl Sagan—"The absence of evidence is not evidence of absence".[397] With respect to the safety of sling surgery, the lack of good studies about the incidence and severity of SMUS complications is not evidence that these complications are uncommon, nor is it evidence that they are not serious. The effectiveness of synthetic slings remains unchallenged, although, as this Review documents, an increasing body of evidence exists that serious and sometimes lifestyle-altering complications are underreported and underappreciated by doctors and patients alike. The true incidence of SMUS-related complications is unknown, owing, in no small part, to the poor overall quality of the studies. Nevertheless, we have calculated the minimum risks: revision surgery for erosion and obstruction alone, 5.6%; chronic pain, 4.3%; recurrent or persistent SUI, 5.3%; and *de novo* refractory OAB 3.9% (Box 1). These data are not mutually exclusive, although we calculated the overall risk of a serious complication or surgical failure to be 12.5%. We emphasize, though, that these data represent the absolute minimum rate of complications reported in the literature; the actual rate might be considerably higher.

Urologists can and must do better in assessing the long-term safety of SMUS surgery and in developing better methods of monitoring patients and assessing the outcomes of treatment for complications, so that both patients and physicians can be advised of the true risks associated with a SMUS.

Review criteria

A systematic review of the English language literature was performed in August 2014 to investigate the published efficacy, effectiveness and complications of SMUS. The search used a complex search strategy of the Medline database, including medical subject heading (MeSH) and free-text protocols. The MeSH search combined the terms "mid urethral sling", "midurethral sling", "suburethral sling", "urethral sling", "mid urethral slings", "midurethral slings", "suburethral slings", "urethral slings" and "follow-up study". Multiple free-text searches included the terms "Urinar*incont*", "TVT", "tension-free vaginal tape*", "Tension-free vaginal sling*", "Transobturator tape*", "Transobturator sling*", "TVT-obturator", "TVT-O", "TVT secure", "miniarc", "abbrevio", "TOT", "suprapubic arc sling*", "SPARC sling*", "intravaginal slingplasty", "IVS sling", "Raz sling", "Uratape", "ObTAPE", "Prepubic sling*", "Prepubic TVT", "Prepubic tape*", "PelviLace", "Ureter", "Aris", "In-Fast", "Monarc", "I-Stop", "urethral reconstruction", "urethrovaginal fistula", "Obtape", "gortex sling", "silastic sling", "mersilene sling", "marlex sling", "vesicovaginal fistula", "BioArc" individually in the fields title and abstract of the records. Subsequently, the search was limited to only human patients. A total of 995 records were retrieved from Medline, 249 were included. Six of the authors reviewed the full texts to select relevant papers. Discrepancies were solved by open discussion. Once the citations were accrued and the papers read, the bibliographies were cross-checked for any relevant citations that were missed in the initial search, which totalled an additional to 88 articles. Only articles published since 2007 were included in the reporting of complications to update and expand upon a review published in 2008.[334] For the section on mesh–body interactions, the search was not limited to humans nor was there a limit on publication date.

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Neurourology and Urodynamics 30:284–291 (2011)

REVIEW ARTICLE

Minimally Invasive Synthetic Suburethral Sling Operations for Stress Urinary Incontinence in Women: A Short Version Cochrane Review

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Background: Stress urinary incontinence (SUI) is a common condition affecting up to 30% of women. Minimally invasive synthetic suburethral sling operations are among the latest forms of procedures introduced to treat SUI. **Objectives:** To assess the effects of minimally invasive synthetic suburethral sling operations for treatment of SUI, urodynamic stress incontinence (USI), or mixed urinary incontinence (MUI) in women. **Search methods:** We searched the Cochrane Incontinence Group Specialised Register (searched March 20, 2008), MEDLINE (January 1950–April 2008), EMBASE (January 1988–April 2008), CINAHL (January 1982–April 2008), AMED (January 1985–April 2008), the UK National Research Register, ClinicalTrials.gov, and reference lists of relevant articles. **Selection criteria:** Randomized or quasi-randomized controlled trials amongst women with SUI, USI, or symptoms of stress or MUI, in which at least one trial arm involved a minimally invasive synthetic suburethral sling operation. **Data collection and analysis:** Two review authors assessed the methodological quality of potentially eligible studies and independently extracted data from the included trials. **Results:** Sixty-two trials involving 7,101 women were included. The quality of evidence was moderate for most trials. Minimally invasive synthetic suburethral sling operations appeared to be as effective as traditional suburethral slings [8 trials, n = 599, risk ratio (RR) 1.03, 95% confidence interval (CI) 0.94–1.13] but with shorter operating time and less postoperative voiding dysfunction and de novo urgency symptoms. Minimally invasive synthetic suburethral sling operations appeared to be as effective as open retropubic colposuspension (subjective cure rate at 12 months RR 0.96, 95% CI: 0.90–1.03; at 5 years RR 0.91, 95% CI: 0.74–1.12) with fewer perioperative complications, less postoperative voiding dysfunction, shorter operative time, and hospital stay but significantly more bladder perforations (6% vs. 1%, RR 4.24, 95% CI: 1.71–10.52). There was conflicting evidence about the effectiveness of minimally invasive synthetic suburethral sling operations compared to laparoscopic colposuspension in the short term (objective cure, RR 1.15, 95% CI: 1.06–1.24; subjective cure RR 1.11, 95% CI: 0.99–1.24). Minimally invasive synthetic suburethral sling operations had significantly less de novo urgency and urgency incontinence, shorter operating time, hospital stay, and time to return to daily activities. A retropubic bottom-to-top route was more effective than top-to-bottom route (RR 1.10, 95% CI: 1.01–1.20; RR 1.06, 95% CI: 1.01–1.11) and incurred significantly less voiding dysfunction, bladder perforations, and tape erosions. Monofilament tapes had significantly higher objective cure rates (RR 1.15, 95% CI: 1.02–1.30) compared to multifilament tapes and fewer tape erosions (1.3% vs. 6% RR 0.25, 95% CI: 0.06–1.00). The obturator route was less favorable than the retropubic route in objective cure (84% vs. 88%; RR 0.96, 95% CI: 0.93–0.99; 17 trials, n = 2,434), although there was no difference in subjective cure rates. However, there was less voiding dysfunction, blood loss, bladder perforation (0.3% vs. 5.5%, RR 0.14, 95% CI: 0.07–0.26), and shorter operating time with the obturator route.

Conflicts of interest: None.
This paper is based on a Cochrane review published in *The Cochrane Library* 2009, Issue 4 (see www.thechochranelibrary.com for information). Cochrane Reviews are regularly updated as new evidence emerges and in response to feedback, and *The Cochrane Library* should be consulted for the most recent version of the review. If you wish to comment on this or other Cochrane Reviews, please use the Cochrane Library Feedback System. The results of a Cochrane Review can be interpreted differently, depending on people's perspectives and circumstances. Please consider the conclusions presented carefully. They are the opinions of the review authors, and are not necessarily shared by The Cochrane Collaboration.
Christopher Chapple led the review process.
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Conclusions: The current evidence base suggests that minimally invasive synthetic suburethral sling operations are as effective as traditional suburethral slings, open retropubic colposuspension and laparoscopic colposuspension in the short-term but with less postoperative complications. Objective cure rates are higher with retropubic tapes than with obturator tapes but retropubic tapes attract more complications. Most of the trials had short-term follow-up and the quality of the evidence was variable. *30:284–291, 2011.* © 2011 Wiley-Liss, Inc.

Key words: stress incontinence; minimally invasive slings; surgery; cochrane review

BACKGROUND

This is an abridged version of a Cochrane review of minimally invasive slings for women with urinary incontinence. Only mid-urethral sling operations, with synthetic tape materials applied by minimally invasive surgeries, either through the retropubic space or the transobturator route were included in this review.

Such slings are only the latest of a long line of operations for stress incontinence. Essentially they fall into seven categories:

- open abdominal retropubic suspension [e.g., colposuspension (Burch/modified Burch), Marshall–Marchetti–Krantz (MMK)][1];
- laparoscopic retropubic suspension[2];
- anterior vaginal repair (anterior colporrhaphy—for example, Kelly, Pacey[3];
- suburethral slings (including traditional suburethral slings and minimally invasive sling operations[4];
- needle suspensions (e.g., Pereyra, Stamey[5];
- peri-urethral injections[6]; and
- artificial sphincters.[7]

See full version of Cochrane Review.[8]

DESCRIPTION OF THE INTERVENTION

A modification of the traditional suburethral sling procedure (Bezerra, 2005), minimally invasive synthetic suburethral sling operations involve the insertion of a tape covered by a plastic sheath around the mid-urethra without suture fixation, performed in some centers under local anesthesia.[9–11] The aim is to restore or enhance the patient's urethral support during a sudden movement, such as a cough or sneeze. This prevents the involuntary loss of urine. The procedure involves the insertion of two needles passed through the retropubic space blindly from vagina to abdomen or from abdomen to vagina. Cystoscopy is recommended to detect any perforation of the bladder or urethra.

In a variation of this procedure, the tape is inserted in a horizontal plane underneath the middle of the urethra between the two obturator foramina. The ends of the tape are tunneled percutaneously with a tunneler (curved needle), again without suture fixation. As the retropubic space is not breached, it is argued that cystoscopy is not required. A further variation involves the passage of a tape through the obturator foramina, from inside to outside.

A concern of using synthetic material is the potential risk of complications caused by infection and tissue reaction to the tapes. Some aspects of the material that may vary include pore size, mono- or multifilament design, and biocompatibility. All types of mesh used in different minimally invasive slings were included in this review and possible differences between the risk of complications were addressed by the outcome measures.

For further detail, see full version of Cochrane review.

OBJECTIVES

To assess the clinical effects of minimally invasive synthetic suburethral sling operations for the treatment of:

1. urodynamic stress urinary incontinence (SUI, urodynamic diagnosis), or for
2. symptoms of stress or mixed incontinence (clinical diagnosis) in women.

The following comparisons were made:

1. Minimally invasive synthetic suburethral sling operations versus traditional suburethral slings.
2. Minimally invasive synthetic suburethral sling operations versus colposuspension (abdominal surgery).
3. Minimally invasive synthetic suburethral sling operations versus laparoscopic procedures.One type of minimally invasive synthetic suburethral sling operations versus another, subgrouped as:
4. Retropubic bottom-to-top approach versus retropubic top-to-bottom approach.
5. Obturator medial-to-lateral approach versus obturator lateral-to-medial approach.
6. Monofilament versus multifilament.
7. Retropubic versus transobturator.
8. Minimally invasive synthetic suburethral sling operations versus no treatment.
9. Minimally invasive synthetic suburethral sling operations versus conservative treatment.

METHODS

See full version of Cochrane review.

RESULTS

We identified 109 studies. Sixty-two of these were randomized trials which met the criteria for inclusion. Full details of the trials and an evaluation of their methodological quality are given in the full version of the Cochrane Review. A further 47 studies were excluded (see Characteristics of excluded studies table in full Cochrane review).

There were no randomized controlled trials comparing minimally invasive synthetic suburethral sling operations with periurethral injection therapy and none compared them with conservative measures such as physiotherapy or lifestyle modification.

The results are limited to cure rates and some adverse effects. For all other outcomes please see full version of Cochrane review.[8]

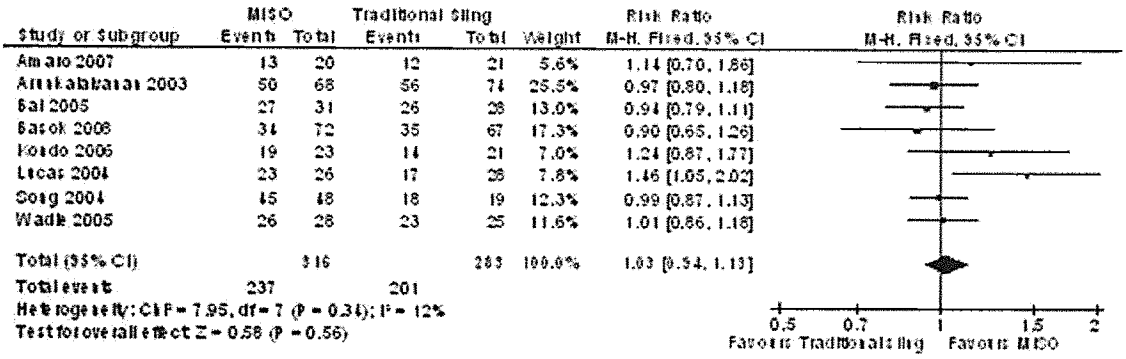

Fig. 1. Minimally invasive synthetic suburethral sling operation versus traditional slings: subjective cure within 12 months.

EFFECTS OF INTERVENTIONS

Minimally Invasive Synthetic Suburethral Sling Operation Versus Traditional suburethral Sling Operation

Nine trials addressed this comparison.[12–20]

There was no statistically significant difference between the subjective cure rates at 1 year: 75% (237/316) of those who had minimally invasive synthetic suburethral sling operations versus 71% (201/283) of those with traditional suburethral sling operations [risk ration (RR) 1.03, 95% confidence interval (CI): 0.94–1.13, Fig. 1].

Adverse effects. There were no statistically significant differences in:

- bladder perforation (RR 2.15, 95% CI: 0.75–6.16, though the confidence interval was wide and we cannot exclude the possibility that there is a big difference favoring traditional slings), or
- tape erosions (none reported in any women in two trials) but the length of follow-up was short.

Minimally invasive Synthetic Suburethral Sling Operation Versus Open Retropubic Colposuspension

Nine trials addressed this comparison.[14,21–28]

Within the first 12 months after surgery, the cure rates were 79% (310/392) with minimally invasive synthetic suburethral sling operations and 82% (277/337) with open colposuspension. However, these were not statistically significantly different (RR 0.96, 95% CI: 0.90–1.03, Fig. 2)

Adverse effects. Ward and Hilton[28] found no significant difference in the likelihood of requiring repeat incontinence surgery (RR 0.52, 95% CI: 0.13–2.12) but women were more likely to need prolapse surgery in the colposuspension group (RR 0.05, 95% CI: 0.00–0.91).

Vaginal tape erosions were reported in 8/249 (3%) women.

There were significantly more bladder perforations with minimally invasive synthetic suburethral sling operations, 6% versus 1% (RR 4.24, 95% CI: 1.71–10.52; Fig. 3) All the perforations in the minimally invasive synthetic suburethral sling operations arm occurred with tension-free vaginal tape (TVT) tapes.

Minimally Invasive Synthetic Suburethral Sling Operation Versus Laparoscopic Colposuspension

Eight trials addressed this comparison.[29–35]

The combined results from six trials showed no statistically significant difference in the reported cure rate between minimally invasive synthetic suburethral sling operations and laparoscopic colposuspension within 12 months (80% vs. 74%, RR 1.11, 95% CI: 0.99–1.24; Fig. 4).

Adverse effects. There was insufficient evidence on repeat incontinence surgery, prolapse surgery, or vaginal erosion. One major vascular injury was reported in the laparoscopic arm of

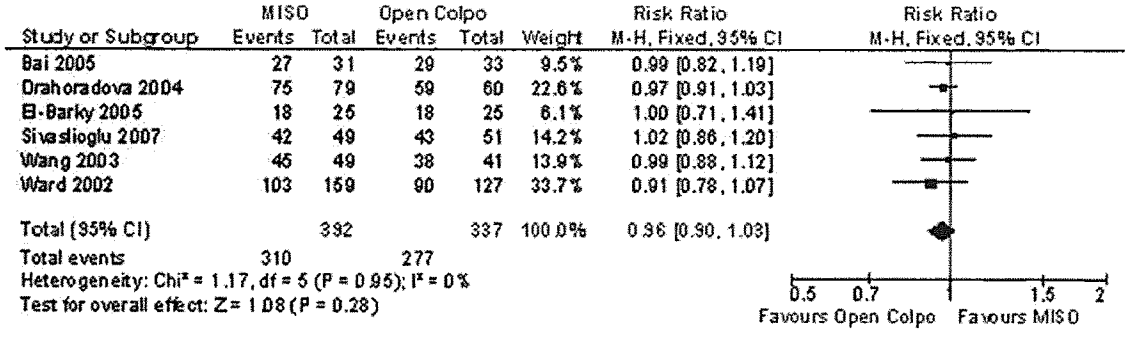

Fig. 2. Minimally invasive synthetic suburethral sling operation versus open colposuspension: subjective cure within 12 months.

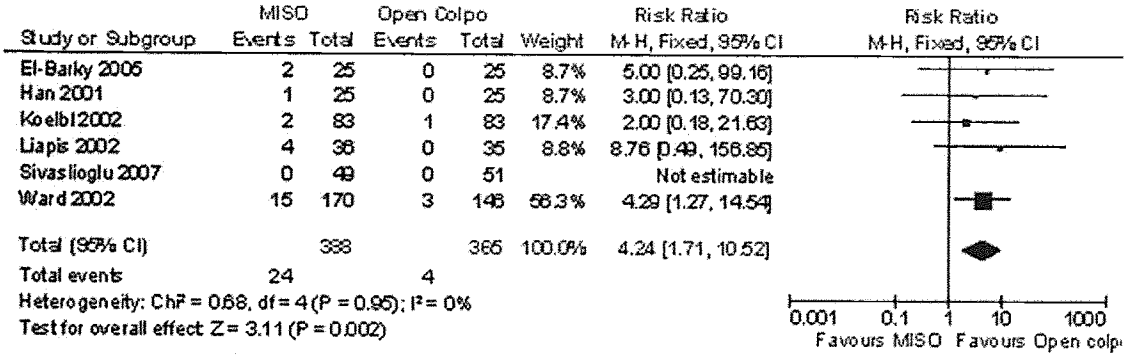

Fig. 3. Minimally invasive synthetic suburethral sling operation versus open colposuspension: bladder or urethral perforation.

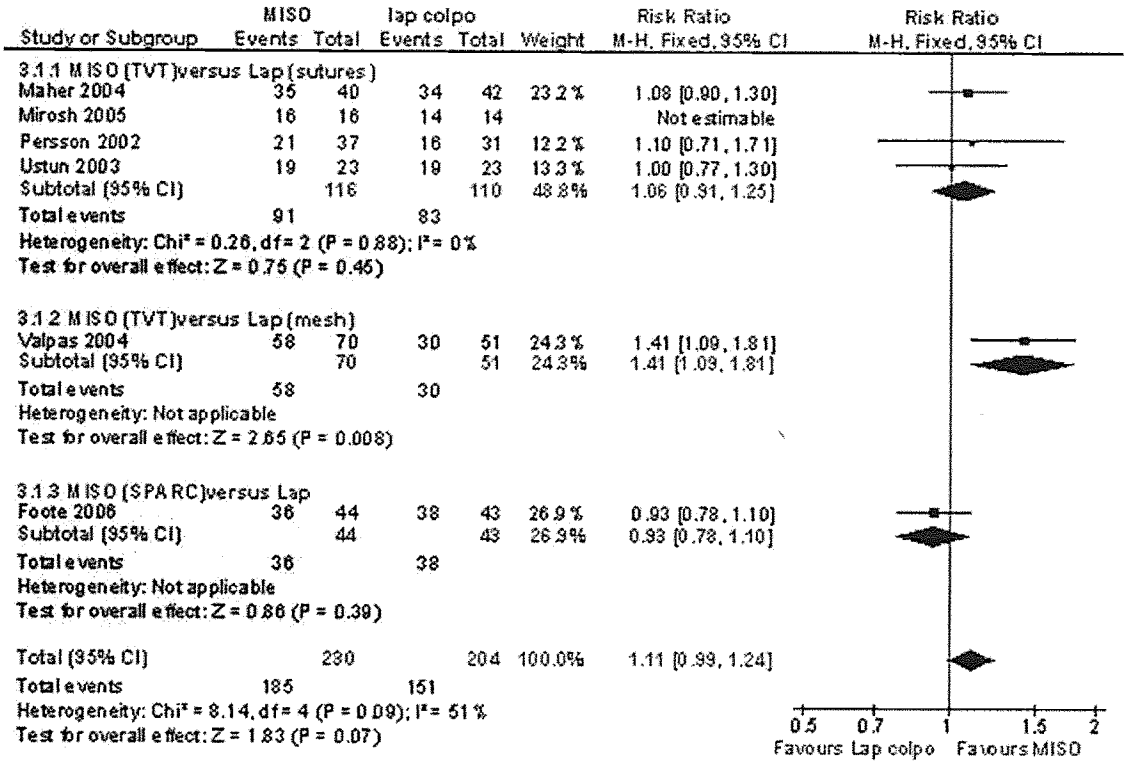

Fig. 4. Minimally invasive synthetic suburethral sling operation versus laparoscopic colposuspension: subjective cure within 12 months.

one trial (Ref.[33] Analysis 3.16). In four trials, the apparent excess of bladder or urethral perforations in the minimally invasive synthetic suburethral sling operations group was not statistically significantly different (RR 2.91, 95% CI: 0.96–8.86, Analysis 3.17A.17) but the confidence interval was wide, so we cannot exclude that laparoscopy could be safer in this respect.

Retropubic Bottom-to-Top Approach (e.g., TVT™) Versus Retropubic Top-to-Bottom Approach (e.g., SPARC™)

Five trials addressed this comparison.[36–40]

Based on both subjective and objective cure rates, women were statistically significantly more likely to be cured with the bottom-to-top approach [e.g., subjective cure rate 85% vs. 77% with top-to-bottom (SPARC™), RR 1.10, 95% CI: 1.01–1.20; Fig. 5].

Adverse effects. Women having the bottom-to-top approach reported fewer adverse effects (bladder perforation, Fig. 6; vaginal erosions; voiding dysfunction; and tape erosions) than with the top-to-bottom approach.

Obturator Medial-to-Lateral Approach (e.g., TOT™) Versus Obturator Lateral-to-Medial Approach (e.g., TVT-O™)

Four small trials addressed this comparison.[41–44]

There were no statistically significant differences in cure or improvement rates, not in adverse effects, between

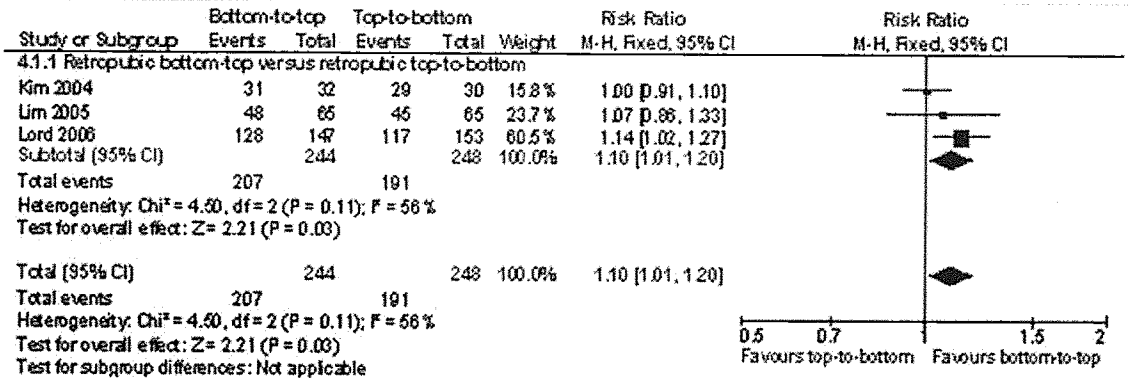

Fig. 5. Retropubic bottom-to-top approach (e.g., TVT™) versus retropubic top-to-bottom approach (e.g., SPARC™): subjective cure within 12 months.

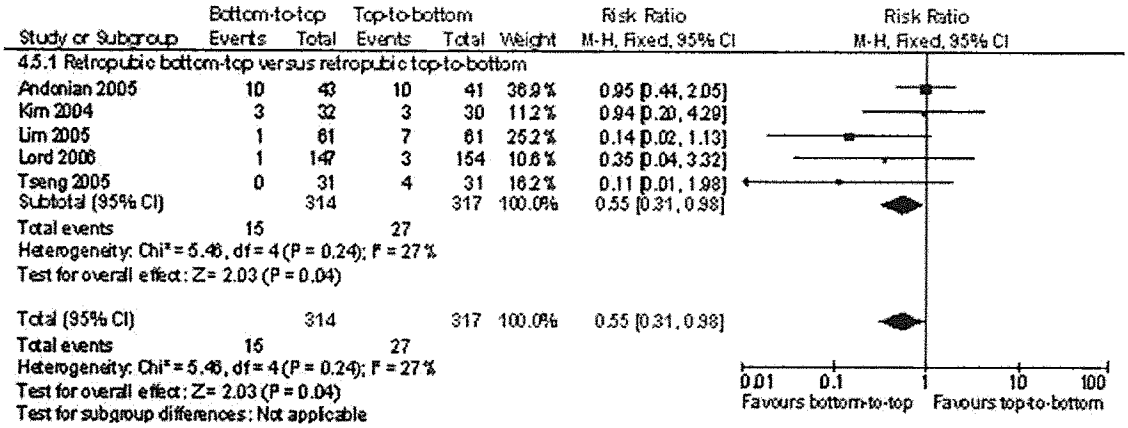

Fig. 6. Retropubic bottom-to-top approach (e.g., TVT™) versus retropubic top-to-bottom approach (e.g., SPARC™): bladder or urethral perforation.

the two approaches but the confidence intervals were wide.

Minimally Invasive Synthetic Suburethral Sling Operations Using Monofilament Versus Multifilament Tape Material

Three trials compared different tape materials directly.[38,45,46]

Women reported higher objective cure rates with monofilament tapes (83% vs. 72%, RR 1.15, 95% CI: 1.02–1.30). Complications were generally few with either type of tape to draw reliable conclusions about adverse effects, although there were fewer erosions with monofilaments (2/153, 1.3% vs. 9/147, 6%).

Transobturator Route Versus Retropubic Route

Twenty-four trials addressed this comparison.[47–69]

The combined result of 10 of these trials, showed there was no statistically significant difference in the subjective cure or improvement rates between the two routes (e.g., cure, RR 1.00, 95% CI: 0.96–1.05). Subjective cure rate in each group was approximately 83%. In this instance, the confidence interval was narrow and may not include a clinically significant difference. The confidence interval is compatible with the relative cure rate for the transobturator route being 5% higher; or being 4% lower than the retropubic route Figure 7.

Adverse effects. The transobturator approach was associated with a shorter operating time, less blood loss, less postoperative voiding dysfunction, and fewer bladder perforations, but more groin pain (12% vs. 1.7%, RR 6, 95% CI: 3–11) than the retropubic route.

DISCUSSION

Overall Completeness and Applicability of Evidence

Many of the trials contributing to this review did provide evidence regarding the primary outcome, which was to determine the effectiveness of minimally invasive synthetic suburethral sling operations in the treatment of urinary incontinence. They confirm that minimally invasive synthetic suburethral sling operations for SUI are as effective as many other surgical treatments available in current practice. A major limitation was the variable quality of many trials.

Certain aspects of the review may be less relevant to some practitioners in other countries. In modern clinical practice in developed nations, increasingly minimally invasive synthetic suburethral sling operations are used as first-line treatment, while inevitably procedures such as open retropubic colposuspension, laparoscopic colposuspension, and

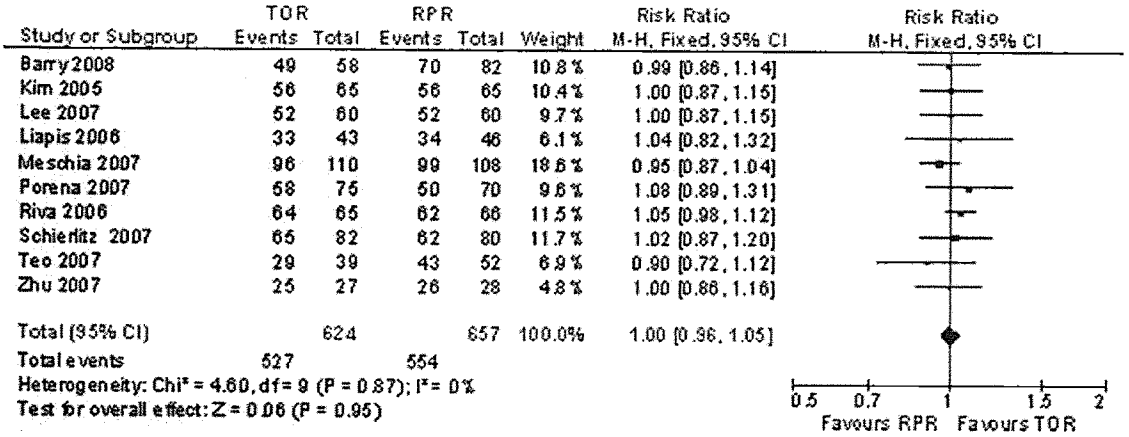

Fig. 7. Transobturator (TOR) versus retropubic (RPR) route: subjective cure within 12 months.

traditional suburethral sling operations are being performed less often. However, these may still be appropriate procedures when minimally invasive synthetic suburethral sling operations technology is not available, or in particular clinical circumstances.

Complications

Major complications such as nerve, bowel or major vascular injuries, pelvic hematoma, necrotizing fasciitis, ischiorectal abscess, and death are uncommon and unlikely to be picked up by small RCTs. The true incidence is more likely to be determined from large national registries and voluntary reporting registries or databases for reporting complications, such as the FDA's manufacturer and user facility device experience (MAUDE). Several of these registries have reported on TVT.[70–72] The number of procedures ranged from 809 to 2,795, and the rate of major complications was low: bladder perforation occurred in 2.7–3.9% of cases (significantly higher in those with previous pelvic organ prolapse or incontinence surgery). There was no record of the sequelae of the perforations.

Reoperation rates relating to tape insertion or postoperative voiding dysfunction ranged from 1.6% to 2.4%; pelvic hematoma occurred in 0.7–1.9% of women, the majority of which needed no intervention, and only one case of bowel injury was recorded. Registries of Transobturator Tapes reported much lower rates of complications (e.g., bladder perforation in 0.4%).[73,74] Reoperation occurred in 0.8–2.2% of women and hematoma occurred in 1 out of 2,543 procedures. Urethral injury rates ranged from 0.08% to 0.1%. It is noteworthy that many of the trials included in our review did not report rates of urethral injuries. This is a rare complication but has significant morbidity and is likely to be under-reported.

Quality of the Evidence

The quality of evidence for the majority of trials was moderate with a minority having low-to-moderate levels of evidence. However, the total number of trials (61, including 7,021 women) was high, and it was possible to explore the effects of different routes of insertion of the tapes and different tape materials. On the other hand, very few trials reported outcomes after 1 year, and the long-term efficacy and adverse effects have yet to be determined.

CONCLUSIONS

Implications for Practice

Minimally invasive synthetic suburethral sling operations are highly efficacious both in the short and medium term for treatment of women with SUI with low rates of complications. Macroporous monofilament sling materials have a better balance of efficacy and adverse reactions when compared to multifilament microporous slings. Retropubic tapes had higher objective cure rates but similar subjective cure rates when compared with transobturator tapes.

Complications studied in this review showed that the use of transobturator tapes had fewer adverse effects compared to retropubic tapes, except for groin pain which occurred more frequently than did suprapubic pain with retropubic tapes, and urethral injury which was not reported in many studies. The conclusion of fewer complications with obturator tapes should be interpreted with some caution as the quality of evidence for the studies is variable, follow-up was short and randomized controlled trials have limitations in identifying true complication rates.

However, there is little evidence about the long-term effectiveness or the chance of adverse effects such as tape erosions. Nor is it clear how to treat women after a tape procedure fails.

Implications for Research

There is a need to address some of the limitations of a number of the trials contributing to this synthesis particularly in improving the methodology of the trials or their reporting. It is highly recommended that clinical trials should be reported following the CONSORT guidelines.

There is a need for more robustly designed good quality and adequately powered randomized controlled trials with standardized objective and validated subjective outcomes. These trials need to have long-term follow-up and adequate reporting of adverse effects. It is essential that outcomes that are relevant to women who have incontinence, and to policy makers who commission treatments, are incorporated into these trials, particularly quality of life and economic implications.

Specific issues that need to be addressed include identifying operations which will reduce the rate of bladder injury particularly in those at higher risk, such as after previous incontinence surgery. A subgroup of women at high risk of voiding

dysfunction, such as those with low or borderline flow rates, should be studied separately.

More trials are required to assess the clinical effectiveness of different tapes in women with urodynamic stress incontinence where hypermobility is differentiated from intrinsic urethral sphincter deficiency.

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Platinum Priority – Female Urology – Incontinence

Editorial by Firouz Daneshgari on pp. 947–948 of this issue

Tension-free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at 10-Year Follow-Up

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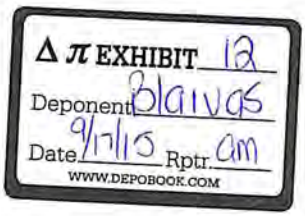

Abstract

Background: One of the most effective and popular current procedures for the surgical treatment of stress urinary incontinence (SUI) is tension-free midurethral slings.
Objective: To evaluate the outcomes of women with retropubic tension-free vaginal tape (TVT) for urodynamic stress incontinence (USI) after 10-yr follow-up.
Design, setting, and participants: This was a prospective observational study. Consecutive women with proven USI were treated with TVT. Patients with mixed incontinence and/or anatomic evidence of pelvic organ prolapse were excluded.
Intervention: Standard retropubic TVT.
Measurements: Patients underwent preoperative clinical and urodynamic evaluations. During follow-up examinations, women were assessed for subjective satisfaction and objective cure rates. Multivariable analyses were performed to investigate outcomes.
Results and limitations: A total of 63 women were included. After 10 yr, 5 patients (8%) were lost or no longer evaluable. The 10-yr subjective, objective, and urodynamic cure rates were 89.7%, 93.1%, and 91.4%, respectively. These rates were stable across the whole study period ($p > 0.99$). De novo overactive bladder was reported by 30.1% and 18.9% of patients at 3-mo and 10-yr follow-up, respectively (p for trend = 0.19). A total of 84.2% of women with detrusor overactivity received antimuscarinic drugs, but 43.8% were nonresponders 12 wk later. At multivariable analysis, maximum detrusor pressure during the filling phase >9 cm H_2O (hazard ratio [HR]: 16.2; $p = 0.01$) and maximum detrusor pressure during the voiding phase ≤29 cm H_2O (HR: 8.0; $p = 0.01$) were independent predictors for the recurrence of SUI, as well as obesity was for the recurrence of objective SUI (HR: 17.1; $p = 0.01$) and of USI (HR: 8.9; $p = 0.02$), respectively. Intraoperatively, bladder perforation occurred in two cases; no severe bleeding or other complications occurred.
Conclusions: The 10-yr results of this study seem to demonstrate that TVT is a highly effective option for the treatment of female SUI, recording a very high cure rate with low complications after a 10-yr follow-up.

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1. Introduction

Retropubic and transobturator tension-free midurethral slings (TVT and transobturator tape TVT-O) represent the most effective and popular procedures for the surgical treatment of stress urinary incontinence (SUI) and are currently considered the gold standard [1].

According to the last 2009 update of the International Consultation on Incontinence Guidelines, the surgical treatments of SUI may include the use of autologous slings, midurethral slings, and colposuspension. The guidelines do not define a clear priority among these three options [2,3]. Similarly, prospective studies, reviews, and meta-analyses [4–6] have highlighted the efficacy and safety of midurethral slings, showing their long-lasting benefits [7,8].

However, the lack of long-term outcomes of surgical procedures for the treatment of urinary incontinence is a major issue of debate in urogynecology. This condition deserves particular interest because life expectancy is significantly improving in the West; therefore data regarding the long-term durability of anti-incontinence procedures such as midurethral slings need to be addressed. To date the available evidence is still limited to only two other publications [7,9].

The aim of the present study is to report the long-term subjective, objective, and urodynamic outcomes of women with TVT with a follow-up of at least 10 yr to assess the efficacy for SUI and the safety of this procedure. We also investigated which factors were potentially involved in the risk of recurrence of SUI and the onset of de novo overactive bladder (OAB).

2. Methods

This prospective study was performed in a single urogynecologic unit at the University of Insubria, Varese, Italy. Between January 2000 and June 2001, we enrolled all consecutive women who complained about symptoms of pure SUI with proven urodynamic stress incontinence (USI). All the patients were candidates for surgery and scheduled for a retropubic TVT procedure (Gynecare; Ethicon, Somerville, NJ, USA). Exclusion criteria were as follows: women with previous history of anti-incontinence or radical pelvic surgery, psychiatric and neurologic disorders, concomitant vaginal prolapse higher than stage 1 according to the Pelvic Organ Prolapse-Quantitative (POP-Q) system [10], OAB symptoms, urodynamically proven detrusor overactivity (DO), and postvoid residual >100 ml.

Preoperative evaluation included medical history, physical examination, a frequency/volume chart, urinalysis, and complete urodynamic testing. The physical examination was performed with the patient in the lithotomic position, and pelvic organ prolapse (POP) was described during a maximal Valsalva maneuver according to the POP-Q system [10]. All women were evaluated with urodynamics (UDS) as previously described [11] (including uroflowmetry, filling cystometry, Valsalva leak point pressure [VLPP] measurement, and pressure/flow study) by a trained urogynecologist using a standardized protocol in accordance with the Good Urodynamic Practices Guidelines of the International Continence Society (ICS) [12]. Urethral hypermobility was defined in the case of a cotton swab test >30°. Patients were included regardless of the cotton swab and VLPP values. All methods, definitions, and units were updated in agreement with the last version ICS standardization of terminology [13].

All the TVT procedures were performed by the same surgeon according to the technique originally described by Ulmsten et al. [14]. The type of anesthesia used was general or spinal, in accordance with the anesthesiologic requirements and/or the patient's preference, as previously reported [15]. Follow-up evaluations were scheduled at 3 and 12 mo, and once per year thereafter, including anamnestic and physical examination, cough test, and evaluation of subjective satisfaction. A cough test was performed in the lithotomic and upright positions with a full bladder (ultrasonographic measurement of at least 400 ml). The objective cure was defined as the absence of urine leakage during a cough test. Subjective satisfaction was defined by using a 3-point symptom assessment scale (0, failure; 1, improved; 2, cured) filled out by the patient herself, as previously reported [16,17]. All women received UDS only at the 10-yr follow up visit, and UDS cure was defined as the absence of urine leakage during provocative maneuvers. Additional UDS, during the other follow-up examinations, was performed only in case of de novo OAB symptoms. For patients with OAB, tolterodine 2 mg twice daily was administered for at least 12 wk, and the efficacy was evaluated using the previously described 3-point symptoms assessment scale. Institutional review board approval and preoperative informed consent were obtained before the beginning of the study by our institution.

2.1. Statistical analysis

Statistical analysis was performed with SPSS v.17 for Windows (IBM Corp., Armonk, NY, USA). Continuous variables were reported as median and interquartile range; the chi-square and Fisher exact test were used to analyze proportions as appropriate. The student *t* test and the Mann-Whitney *U* test were performed to compare continuous parametric and nonparametric variables, as appropriate. The Cox proportional hazard model was used for univariable and multivariable analyses to evaluate factors potentially affecting the risk of recurrence (subjective, objective, and urodynamic).

Finally, multinomial logistic regression using the stepwise analysis was performed to investigate independent predictors of de novo OAB development. All the covariates that had p values ≤ 0.05 in univariable analysis were entered into the multivariate model using forward stepwise analysis. For both multivariable models, variables of interest were dichotomized either arbitrarily (ie, elderly: age ≥65 yr; obesity: body mass index [BMI] ≥30 kg/m^2) or using receiver operating characteristic curves (ie, UDS parameters). Statistical significance was considered achieved when $p < 0.05$.

3. Results

During the study period, 207 women were assessed for SUI at our department. Among these patients, 144 were excluded for the following reasons: 53 had mixed incontinence and 91 had concomitant evidence of POP. A total of 63 patients with proven USI who fulfilled the inclusion and exclusion criteria underwent the TVT procedure. Figure 1 displays the overall study flowchart. Table 1 summarizes the baseline characteristics of the study group.

Intraoperatively, bladder perforation occurred in two cases (3.8%). In both situations the bladder lesion was identified during the operation and the tape was promptly removed and replaced. No severe bleeding or other intraoperative complications occurred. No postoperative complications requiring surgical reintervention occurred.

At 10-yr follow-up, 58 cases (92.0%) were available for evaluation, whereas 5 patients (8.0%) were lost to follow-up or were no longer evaluable; 3 of them died for medical reasons not related to the TVT procedure (1 after the

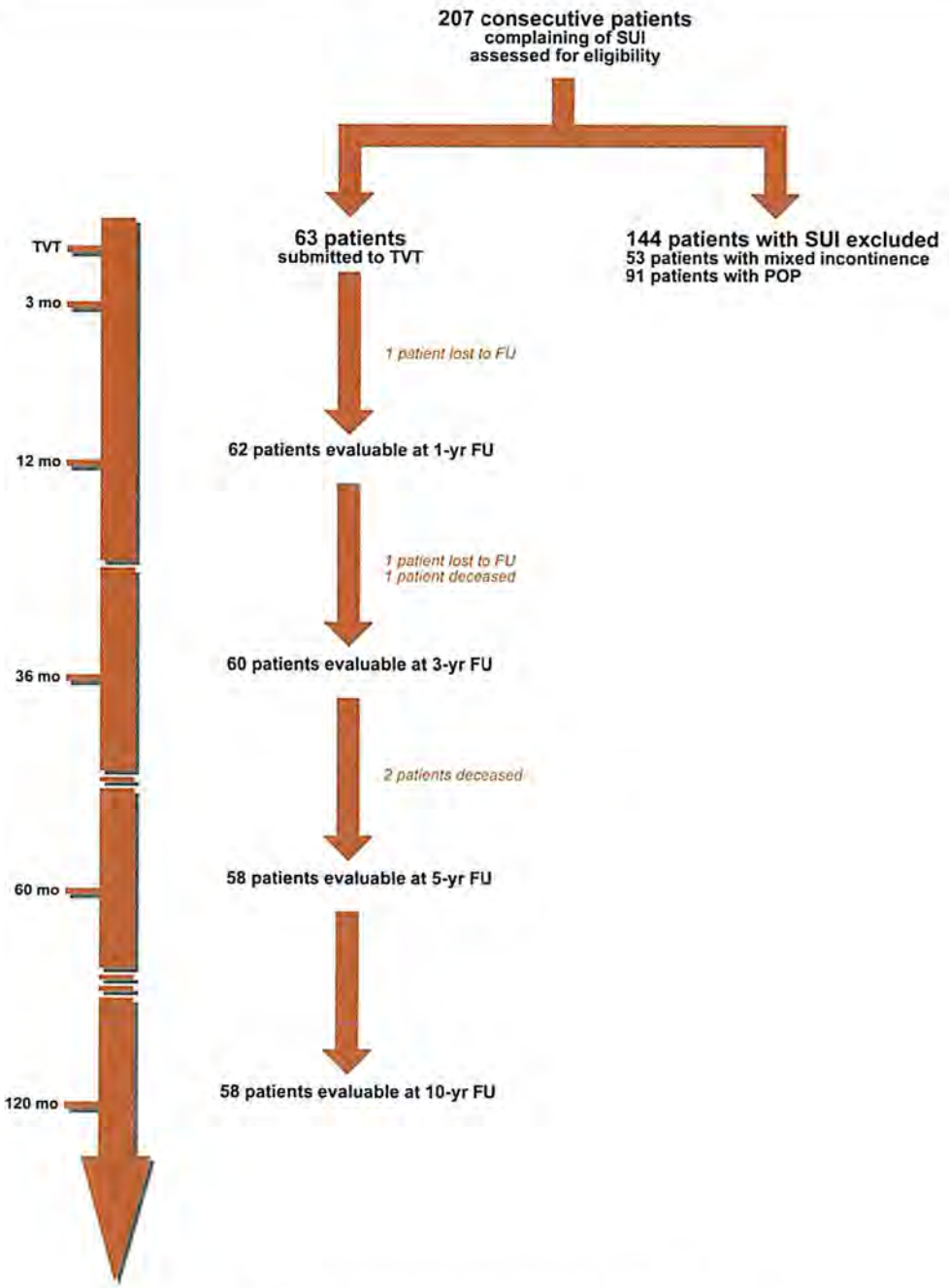

Fig. 1 – Progress of patients across the study period.
FU = follow-up; POP = pelvic organ prolapse; SUI = stress urinary incontinence.

first-year examination and 2 after the third-year examination, respectively), and 2 were lost to follow-up (1 after 3 mo and 1 after a year, respectively). However, at their last evaluation, these five women were subjectively and objectively cured.

Table 2 summarizes the subjective satisfaction and objective cure rate across the follow-up period. No significant deterioration of either subjective or objective outcomes was observed over time (all p values > 0.99). Ten years after surgery, 52 of 58 patients (89.7%) declared themselves satisfied, and 54 of 58 (93.1%) were at least improved. Similarly, at the last evaluation 54 of 58 women (93.1%) were objectively cured, and 53 of 58 (91.4%) also confirmed this finding at UDS.

Table 3 reports the univariable and multivariable analyses of factors potentially involved in the risk of recurrent subjective, objective, and UDS stress incontinence along the follow-up. Obesity, cystometric capacity, maximum detrusor pressure during filling and during voiding phases, maximum flow rate, intravesical opening pressure, and detrusor pressure at maximum flow rate were all significantly associated with subjective recurrent SUI in univariable analyses (all p values <0.05). On multivariable analyses, maximum detrusor pressure during the filling

Table 1 – Baseline characteristics†

	n = 63
Age, yr	58 (48–69)
BMI, kg/m²	27 (26–28)
Obese: BMI ≥30 kg/m²	9 (14.2)
Sexually active	42 (66.6)
Menopausal	45 (71.4)
HRT	18 (28.6)
Recurrent UTI	9 (14.2)
Previous vaginal deliveries	2 (2–3)
Macrosome (≥4000 g)	17 (27.0)
Operative delivery (vacuum/forceps)	7 (11.1)
Previous hysterectomy	7 (11.1)
Urethral hypermobility*	53 (84.1)
VLPP <60 cm H_2O	36 (57.1)

BMI = body mass index; HRT = hormonal replacement therapy; UTI = urinary tract infection; VLPP = Valsalva leak point pressure.
† Data are expressed as absolute number (%) or median (interquartile range).
* Cotton swab test >30°.

phase >9 cm H_2O (hazard ratio [HR]: 16.2; $p = 0.01$] and maximum detrusor pressure during the voiding phase ≤29 cm H_2O (HR 8.0; $p = 0.01$] at the preoperative UDS were the only independent predictors of recurrence of SUI. Obesity represented the only independent predictor of objective recurrence of SUI (HR 17.1; $p = 0.01$) and of recurrent USI (HR: 8.9; $p = 0.02$).

The onset of de novo OAB symptoms was reported by 30.1% (19 of 63) and 18.9% (11 of 58) at 3-mo and 10-yr follow-up, respectively. This proportion did not significantly change across the study period (p for trend: 0.19). All these women presented with dry OAB. At the UDS evaluation, 17 of 19 women (89.5%) had DO; 84.2% (16 of 19) of these women started an antimuscarinic treatment. Twelve weeks later, 43.8% (7 of 16) were nonresponders.

Univariable and multivariable analyses were performed to evaluate variables predicting the risk of de novo OAB at 3 mo and 10 yr. A first desire to void <190 ml (odds ratio [OR]: 7.1; $p = 0.01$) and a maximum detrusor pressure during voiding >28 cm H_2O (OR: 8.1; $p = 0.009$) at the preoperative UDS were both independent predictors for the onset of de novo OAB 3 mo after surgery. Similarly, a maximum detrusor pressure during the filling phase >8 cm H_2O (OR 7.9; $p = 0.02$) predicted the OAB at 10 yr (Table 4).

At 10-yr follow-up, comparing the pre- and post-TVT urodynamic data, we only found a significantly higher detrusor pressure during the filling and during the voiding phase; this finding reflects the onset of de novo DO in 17 women (Table 5).

During the final visit, voiding difficulties were reported in two patients. No patient required tape release or section during the 10-yr follow-up. No significant POP, vaginal, bladder, or urethral erosion, or de novo dyspareunia were noted in the remaining 58 patients.

4. Discussion

This study reports the combination of subjective, objective, and urodynamic outcomes of retropubic TVT at 10-yr follow-up. We found TVT to be a highly effective and safe procedure, with a long lasting effectiveness over time.

In the last decade, several publications have demonstrated the efficacy of this treatment at 1, 3, 5, and 7 yr [8,18–23]. However, for the comparison of the outcomes between the TVT and other historical procedures for the treatment of SUI such as open colposuspension, long-term follow-up is mandatory. In the present series the efficacy of TVT was also not affected in the long-term period. Such data are in agreement with the very few studies available in the

Table 2 – Analysis of cure rates across the study period

	3 mo	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	p value
Subjective outcomes												
Satisfied only	93.7 (59/63)	93.5 (58/62)	93.5 (58/62)	91.7 (55/60)	91.7 (55/60)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	89.7 (52/58)	0.99*
Satisfied plus improved	95.2 (60/63)	95.2 (59/62)	95.2 (59/62)	93.3 (56/60)	93.3 (56/60)	94.8 (55/58)	94.8 (55/58)	94.8 (55/58)	94.8 (55/58)	94.8 (55/58)	93.1 (54/58)	0.99*
Satisfied only Assuming lost as failures	93.7 (59/63)	92.1 (58/63)	92.1 (58/63)	87.3 (55/63)	87.3 (55/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	82.5 (52/63)	0.63*
Satisfied only Assuming lost as the last result carried forward	93.7 (59/63)	93.7 (59/63)	93.7 (59/63)	93.7 (59/63)	93.7 (59/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	88.9 (56/63)	0.73*
Objective outcomes												
Objectively cured (at stress test)	95.2 (60/63)	95.2 (59/62)	95.2 (59/62)	91.7 (55/60)	91.7 (55/60)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	0.99*
Objectively cured Assuming lost as failure	95.2 (60/63)	93.7 (59/63)	93.7 (59/63)	87.3 (55/63)	87.3 (55/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	0.53*
Objectively cured Assuming lost as last result carried forward	95.2 (60/63)	95.2 (60/63)	95.2 (60/63)	93.7 (59/63)	93.7 (59/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	0.99*
De novo OAB												
Onset of OAB	30.2 (19/63)	22.6 (14/62)	19.4 (12/62)	18.3 (11/60)	18.3 (11/60)	18.9 (11/58)	18.9 (11/58)	18.9 (11/58)	18.9 (11/58)	18.9 (11/58)	18.9 (11/58)	0.91*

OAB = overactive bladder.
* Chi-square test.

s of variables potentially involved in the risk of recurrence of stress incontinence

jective recurrence of SUI			Objective recurrence of stress incontinence				Urodynamics recurrence of USI			
alysis*	Multivariable analysis†		Univariable analysis*		Multivariable analysis†		Univariable analysis*		Multivariable analysis†	
p value	Hazard ratio (95% CI)	*p* value	Hazard ratio (95% CI)	*p* value	Hazard ratio (95% CI)	*p* value	Hazard ratio (95% CI)	*p* value	Hazard ratio (95% CI)	Macrosome value
0.68	–		0.6 (0.1–5.5)	0.62	–		0.43 (0.04–3.8)	0.45	–	
0.04	–	NS	17.1 (1.8–163)	0.007	17.1 (1.8–163)	0.01	8.9 (1.5–52.9)	0.02	8.9 (1.5–52.9)	0.02
0.83	–		0.99 (0.1–9.5)	0.99	–		0.5 (0.1–2.9)	0.44	–	
0.35	–		0.5 (0. 1–2.7)	0.96	–		0.5 (0. 1–2.4)	0.35	–	
0.90	–		0.2 (0.1–10.4)	0.97	–		1.8 (0.2–15.3)	0.62	–	
0.86	–		0.3 (0.04–2.4)	0.27	–		0.5 (0.1–2.9)	0.44	–	
0.88	–		0.9 (0.2–4.5)	0.88	–		0.9 (0.2–4.5)	0.88	–	
0.98	–		1.01 (0.1–9.1)	0.98	–		1.5 (0.2–13.6)	0.69	–	
0.87	–		1.2 (0.1–12.0)	0.87	–		1.8 (0.2–15.9)	0.59	–	
0.39	–		0.6 (0.06–5.6)	0.64	–		0.3 (0.04–1.7)	0.17	–	
0.48	–		0.5 (0.05–4.6)	0.53	–		0.97 (0.2–5.8)	0.97	–	
0.22	–		3.1 (0.3–29.8)	0.32	–		4.2 (0.5–16.9)	0.20	–	
0.03	–	NS	1.9 (0.2–13.2)	0.52	–		2.8 (0.5–16.9)	0.25	–	
0.007	16.2 (1.9–136)	0.01	4.7 (0.5–45.5)	0.17	–		6.4 (0.7–57.1)	0.09	–	
0.02	–	NS	5.6 (0.3–28.7)	0.95	–		5.6 (0.3–28.7)	0.95	–	
0.02	–	NS	6.2 (0.3–28.3)	0.95	–		2.6 (0.1–8.2)	0.95	–	
0.04	8.0 (1.5–41.0)	0.01	5.0 (0.1–14.2)	0.94	–		7.2 (0.8–64.4)	0.07	–	
0.30	–		0.95 (0.1–9.1)	0.96	–		1.8 (0.3–11.2)	0.48	–	

amic stress incontinence; CI = confidence interval; BMI = body mass index; HRT = hormone replacement therapy; UTI = urinary tract infection; VLPP = Valsalva leak point metric capacity; Q_{max} = maximum flow rate; I-OpenP = intravesical opening pressure; $Pdet_{max}$ = maximum detrusor pressure; $Pdet_{Qmax}$ = detrusor pressure at maximum flow

l stepwise analysis.

Table 4 – Uni- and multivariable analyses of variables potentially involved in the risk of onset of de novo overactive bladder

Variables	De novo OAB after 3 mo				De novo OAB after 10 yr			
	Univariable analysis*		Multivariable analysis†		Univariable analysis*		Multivariable†	
	Odds ratio (95% CI)	*p* value	Odds ratio (95% CI)	*p* value	Odds ratio (95% CI)	*p* value	Odds ratio (95% CI)	*p* value
Elderly: age ≥65 yr	1.1 (0.3–3.4)	>0.99	–		0.4 (0.07–1.8)	0.30	–	
Obese: BMI ≥30 kg/m^2	1.1 (0.2–4.9)	>0.99	–		2.1 (0.4–10.1)	0.38	–	
No. of vaginal deliveries ($n \geq 2$)	1.2 (0.3–4.2)	0.76	–		0.5 (0.1–2.0)	0.43	–	
Macrosome (≥4000 g)	0.9 (0.3–3.0)	>0.99	–		1.6 (0.4–6.3)	0.71	–	
Operative delivery	0.9 (0.1–4.9)	>0.99	–		3.8 (0.7–20.6)	0.13	–	
Menopausal	0.6 (0.2–2.1)	0.52	–		0.9 (0.2–4.3)	>0.99	–	
HRT	0.8 (0.2–2.6)	0.77	–		0.8 (0.2–3.6)	>0.99	–	
Recurrent UTI	1.3 (0.3–6.2)	0.70	–		6.1 (1.2–30.4)	0.03	–	NS
Previous hysterectomy	1.7 (0.3–8.4)	0.67	–		4.0 (0.8–21.6)	0.11	–	
Urethral hypermobility	5.2 (0.6–44.7)	0.14	–		0.9 (0.2–5.1)	>0.99	–	
VLPP <60 cm H_2O	0.8 (0.3–2.4)	0.78	–		1.2 (0.3–4.6)	>0.99	–	
FDTV (≤190 ml)	4.2 (1.3–13.9)	0.025	7.1 (1.5–33.3)	0.01	1.3 (0.3–4.7)	>0.99	–	
CC (>496 ml)	0.2 (0.06–0.8)	0.046	0.2 (0.04–0.8)	0.02	0.1 (0.03–0.63)	0.01	0.1 (0.02–0.8)	0.01
$Pdet_{max}$ during filling phase (>8 cm H_2O)	3.3 (1.02–10.3)	0.053	–		6.6 (1.3–34.2)	0.02	7.9 (1.3–47.6)	0.02
Q_{max} (>17 ml/s)	1.5 (0.4–5.1)	0.56	–		2.6 (0.5–13.2)	0.31	–	
I-OpenP (≤28 cm H_2O)	21.3 (1.2–380.1)	0.002	–	NS	3.8 (0.4–32.9)	0.26	–	
$Pdet_{max}$ during voiding (>28 cm H_2O)	3.3 (1.2–11.2)	0.07	8.1 (1.7–39.5)	0.009	0.7 (0.2–2.9)	0.72	–	
$Pdet_{Qmax}$ (≤31 cm H_2O)	17.1 (1.02–306.4)	0.006	–	NS	3.1 (0.4–26.6)	0.43	–	

OAR = overactive bladder; CI = confidence interval; BMI = body mass index; HRT = hormone replacement therapy; UTI = urinary tract infection; VLPP = Valsalva leak point pressure; FDTV = first desire to void; CC = cystometric capacity; $Pdet_{max}$ = maximum detrusor pressure; Q_{max} = maximum flow rate; I-OpenP = intravesical opening pressure; $Pdet_{Qmax}$ = detrusor pressure at maximum flow rate.
* Fisher exact test.
† Binary logistic regression with forward stepwise analysis.

literature. Specifically, Nilsson et al. reported 11-yr follow-up data of TVT in 90 women with SUI that demonstrated objective and subjective cure rates as high as 90% and 77%, respectively [7]. Similarly, Olsson and colleagues found an objective cure rate of 84% and a subjective cure rate of 77% with 94% of the included patients satisfied with the results achieved [9]. However, a not negligible proportion of women included in these studies were evaluated during the last follow-up visit only by phone or by mail [7,9]. Conversely, to our knowledge, we present for the first time a comprehensive subjective, clinically objective, and urodynamic outcome of TVT at 10-yr follow-up. We also must emphasize that those women ($n = 6$) who were subjectively not satisfied after 10 yr in our study did not require any other surgical treatment.

Table 5 – Comparison of the urodynamic data†

	Preoperative UDS	UDS at 10 yr	*p* value*
FDTV, ml	180 (50–430)	195 (50–430)	>0.99
CC, ml	480 (220–500)	480 (220–500)	0.29
$Pdet_{max}$ during filling phase (cm H_2O)	8.4 (3–15)	9.5 (3–32)	0.001
Q_{max} (ml/s)	21 (7–77)	22 (7–67)	0.68
I-OpenP (cm H_2O)	23.4 (9–66)	23.2 (9–66)	0.98
$Pdet_{max}$ during voiding (cm H_2O)	31.5 (10–75)	32.1 (10–75)	0.01
$Pdet_{Qmax}$ (cm H_2O)	24.4 (8–60)	25.3 (8–59)	0.02

UDS = urodynamics; FDTV = first desire to void; CC = cystometric capacity; $Pdet_{max}$ = maximum detrusor pressure; Q_{max} = maximum flow rate; I-OpenP = intravesical opening pressure; $Pdet_{Qmax}$ = detrusor pressure at maximum flow rate.
† Data are expressed as median (range).
* Wilcoxon matched paired test.

The onset of de novo OAB symptoms, together with their progression and their possible treatment, is one of the most clinically relevant and largely debated postoperative complications of midurethral slings. Previous studies have reported de novo urgency rates ranging from 4% to 33% after TVT [5,20,24,25]. Discrepancies are related to the different definitions and questionnaires adopted to collect OAB symptoms, different demographic characteristics of the women included, and different concomitant surgical procedures associated with TVT. However, in our series we recorded a high prevalence of de novo OAB especially in the early postoperative period (about 30% at 3-mo follow-up). Conversely, we noted stable or even a lower prevalence of OAB symptoms over time, despite aging of the patients. For most of the patients complaining about de novo OAB, urodynamically proven DO was the underlining pathophysiologic condition. For the first time in the literature, we evaluated the efficacy of antimuscarinics in this particular type of symptomatic DO, identifying a cure rate lower than compared with idiopathic OAB [16,17,26]. At present the real efficacy of antimuscarinic treatment in OAB symptom subsequent to SUI surgery is difficult to define due to the lack of studies other than the present one. Such a crucial clinical issue deserves further investigation.

We have also considered several demographic, clinical, and urodynamic data to identify which factors could be involved in the risk of recurrence of stress incontinence or

development of de novo OAB. We found that women with a maximal detrusor pressure ($Pdet_{max}$) during voiding ≤29 cm H_2O at preoperative urodynamics were associated with a significantly higher incidence of SUI recurrence. We could speculate that in these women the lower $Pdet_{max}$ could reflect the lower pressure exerted to overcome urethral resistance during micturition, showing therefore a lower rhabdosphincter function. In our population, neither VLPP nor urethral mobility was an independent predictor for the recurrence of SUI. There are currently diverging opinions regarding the role of obesity on the outcomes of TVT [27–29]; in our population obesity was the only independent predictor of objective and urodynamic recurrence of stress incontinence, therefore confirming a significant association between BMI and the pathophysiology of SUI.

We also observed that higher preoperative detrusor pressure values (both during the filling and voiding phase) independently predicted the onset of de novo OAB. Comparing the urodynamic findings at the 10-yr follow-up with the preoperative data, we registered higher values of detrusor pressures, thus reflecting the onset of de novo DO.

The present study has several strengths including (1) a clinical and urodynamic evaluation performed in all patients 10 yr after TVT; (2) a highly homogeneous study population with the exclusion of women with mixed incontinence, DO, and/or any other associated surgical procedure; (3) the subjective and objective outcomes available for every year, and (4) the pre- and postoperative urodynamic evaluation. We acknowledge that a weakness of this study could be the limited sample size, even if patients were recruited in just one urogynecologic center, with an impressively low percentage of women lost to follow-up. For the present study no quantitative evaluation by any questionnaire was used because no validated instrument in Italian language was available in 2000. Another limitation of the present study is the three-item scale used to assess patients' perceptions of symptoms; it could be considered inadequate to detect small changes in patient conditions. However, Burgio et al. [30] reported a comparison among three subjective outcome tools as a secondary analysis of data from three randomized controlled trials testing interventions for incontinence. They evaluated a patient satisfaction questionnaire (a three-item scale) similar to the one we used in this study, a global perception of improvement (a five-item scale), and an estimated percentage of improvement (a scale from 0% to 100%). They concluded that all three of these instruments have "acceptable convergent and discriminant validity for measuring outcomes in studies of treatment for urinary incontinence" [30]. Finally, due to the limited number of events, we were forced to use stepwise multivariable models, which are well known to inflate the prognostic role of the covariates left in the models. However, a different choice would have resulted in overfitted models.

5. Conclusions

The long-term results of this prospective observational study seem to demonstrate that the TVT is a highly effective option for the treatment of female SUI. Indeed, we recorded very high cure rates and low complication rates over the 10-yr observation. The early postoperative onset of de novo OAB symptoms, especially if persisting over the years, could be the most relevant clinical issue related to TVT.

Author contributions: Maurizio Serati had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Serati.
Acquisition of data: Serati, Cattoni, Braga.
Analysis and interpretation of data: Serati, Siesto, Torella, Cromi.
Drafting of the manuscript: Serati, Cattoni.
Critical revision of the manuscript for important intellectual content: Serati, Ghezzi, Vitobello, Salvatore.
Statistical analysis: Serati, Siesto.
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Supervision: None.
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Original Article: Clinical Investigation

Tension-free vaginal tape procedure without preoperative urodynamic examination: Long-term outcome

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Abbreviations & Acronyms
BMI = body mass index
DIS = Detrusor Instability Score
EQ-5D VAS = European quality of life – visual analog scale
EuroQoL-5D = European quality of life-five dimensions
IIQ-7 = Incontinence Impact Questionnaire-7
ISD = intrinsic sphincteric deficiency
MUI = mixed urinary incontinence
NS = not significant
SD = standard deviation
SUI = stress urinary incontinence
TOT = transobturator tape
TVT = tension-free vaginal tape
UDI-6 = Urogenital Distress Inventory-6
UISS = Urinary Incontinence Severity Score
UUI = urgency urinary incontinence
VAS = visual analog scale

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Objectives: To evaluate the long-term outcome of the tension-free vaginal tape procedure.

Methods: A total of 191 patients were operated on with tension-free vaginal tape between January 1998 and May 2000. Of these, 127 (66%) had stress urinary incontinence, 64 (34%) had mixed urinary incontinence and 39 (20%) had recurrent incontinence. A total of 34 (18%) patients had had concomitant surgery. The diagnosis of incontinence was based on a history of leakage during stress and physical examination with a supine stress test in all patients. Tension-free vaginal tape was carried out under local (82%) or spinal (18%) anesthesia. After a mean of 10.5 years follow up, the assessment included a gynecological examination and a supine stress test. Subjective outcome was evaluated with Urinary Incontinence Severity Score, Detrusor Instability Score, visual analog scale, European quality of life-five dimensions, European quality of life – visual analog scale and short versions of Incontinence Impact Questionnaire-7 and Urogenital Distress Inventory-6. Objective cure was defined as a negative stress test and an absence of reoperation for incontinence during the follow up.

Results: A total of 138 (72%) of 191 patients were evaluated. Patients with minimally invasive surgery before operation had significantly higher scores in Urinary Incontinence Severity Score, Detrusor Instability Score, Incontinence Impact Questionnaire-7 and Urogenital Distress Inventory-6 at follow up than the patients with stress urinary incontinence ($P < 0.01$). Recurrent incontinence and concomitant surgery did not affect the long-term outcome. Three patients (2.3%) had late-onset adverse events. The objective and subjective cure rates were 90% and 78%, respectively.

Conclusions: The tension-free vaginal tape procedure is effective and safe even after 10 years. The objective cure rate is high, but the subjective outcome is significantly lower in mixed urinary incontinence patients compared with patients with pure stress urinary incontinence. Recurrent stress urinary incontinence does not affect the outcome, and tape-related problems are rare.

Key words: follow-up studies, minimally invasive surgery, stress urinary incontinence, suburethral slings, tension-free vaginal tape.

Introduction

The overall prevalence of female SUI among females over the age of 18 years is approximately 30%,[1] but is increasing with age.[2] SUI can be treated surgically, and minimally invasive techniques have been developed to minimize surgical complications, and to improve outcome and patient satisfaction. The TVT technique was introduced by Ulmsten in 1996, and has become the gold standard for treating female SUI.[3] In TVT, a tape is placed loosely under the midurethra through the retropubic space. According to the few long-term follow-up studies that are available, cure rates have been satisfying for TVT and mesh-related adverse events are rare.[4,5]

The aim of the present study was to report the effectiveness, subjective and objective outcomes, and late adverse events among patients who underwent TVT a mean of 10.5 years

ago without preoperative urodynamic examination. The short-term outcome of the present study population has already been published.[6]

Methods

The present study is a follow-up study of 191 patients operated on with the TVT procedure between January 1998 and May 2000 at the Department of Obstetrics and Gynecology in the Turku City Hospital, Turku, Finland. The Departments of Obstetrics and Gynecology of the Turku City Hospital and of the University Hospital were joined in 2004, and therefore this follow up was not carried out in the same hospital as the original operation. All the operations were carried out by senior gynecologists. Most (90%) of the procedures were carried out by one surgeon (PK). The study population has been presented previously.[6] A total of 127 patients (66%) had SUI and 64 (34%) had MUI with SUI symptoms dominating. In the original cohort, 39 (20%) patients had recurrent incontinence with previous anti-incontinence operations, which were colposuspension in 23 cases (19 open and 4 laparoscopic), vaginal incontinence operation in 12 (including one TVT) and periurethral injection in six patients. Furthermore, one patient had undergone bladder neck discision because of retention and overflow incontinence.

The diagnosis of incontinence was based on a history of leakage during stress and physical examination with a supine stress test in all patients. In over half of the cases the UISS[7] (Appendix 1), the DIS[7,8] (Appendix 2) was also filled in. Urogynecological perineal ultrasonography was carried out to examine the patients who had a history of MUI in order to verify the SUI component.[9] Also, of the 39 patients with recurrent incontinence, 22 patients underwent preoperative ultrasonography. In the original study population, all patients were primarily treated with pelvic floor exercise including instructions for bladder training and secondarily with anti-cholinergic medication if required.[6]

Vaginal, systemic or combined hormone replacement therapy was used by 119 (62%) patients. The procedure was carried out as previously described[3] under local (82%) or spinal (18%) anesthesia with perioperative cystoscopy. The tape (TVT Gynecare; Ethicon, Somerville, NJ, USA) was loosely placed under the midurethra. An intraoperative stress test with 300 mL bladder filling was used to adjust the tape in all patients regardless of the method of anesthesia. One dose of 500 mg metronidazole was given intravenously for antibiotic prophylaxis immediately before the operation. Concomitant surgery was carried out in 34 (18%) patients; 13 procedures were carried out for pelvic organ prolapse and 21 vaginal hysterectomies were carried out because of heavy bleeding or uterine fibroids.

After a mean of 10.5 years (range 9–12 years), postal questionnaires were sent to all patients together with an invitation for a charge-free follow-up visit at the Turku University Hospital, Outpatient Clinic of Gynecology. A reminder was sent to those who did not respond to the first questionnaire. Attempts were made to contact non-respondents by telephone. They were asked about symptoms of SUI, urgency or UUI and any late adverse events, as well as satisfaction with the operation.

Subjective outcome was evaluated with condition-specific questionnaires: the UISS, the DIS, short versions of the IIQ-7 and the UDI-6, and a VAS 0–100.[10] UISS and DIS have been designed by the urogynecological working groups of Finnish and Nordic Gynecological Societies. UISS demonstrates symptom severity and the impact of urinary incontinence on everyday life, and DIS symptoms of detrusor instability and its degree. These questionnaires are widely used in Finland, as in other Scandinavian countries.[7,8] In the DIS questionnaire, scores ≤ 7 refer to pure SUI and the more scores that are calculated, the more symptoms of urgency exists.[8] The patients' general quality of life and health was assessed with EQ-5D and EQ-5D VAS. If a patient left more than two items unanswered in the IIQ-7 or UDI-6 questionnaires, a total score was not calculated. The patient was considered to be satisfied with the procedure if the total score of the IIQ-7 questionnaire was 0–7[11] and if they expressed satisfaction at the telephone interview. If the score in the DIS questionnaire was more than 7, and if the patient had moderate or severe frequency or urgency (scores 2 or 3) in questions one and two of the UDI-6 questionnaire, the patient was considered to have urgency or UUI.

At the follow-up visit, a gynecological examination and a supine stress test with a 250–300 mL bladder volume were carried out. The hospital records of all the patients were reviewed to examine whether the patients had had visits to the hospitals in the Hospital District of Southwest Finland. This was done to acquire information on later acquired systemic diseases, gynecological or anti-incontinence operations, urinary symptoms and adverse events after the TVT-operation.

Objective cure was defined as a negative stress test and no need for a reoperation for SUI.

The SAS system for Windows version 9.2 (SAS Institute, Cary, NC, USA) was used for tabulations and statistical analysis.

The study was approved by the Ethics Committee of the Hospital District of Southwest Finland.

Results

A total of 138 (72%) out of 191 patients were evaluated at a mean of 10.5 years postoperatively (Fig. 1). Of these, 127 (66% of the original cohort) both answered the questionnaires and visited the outpatient clinic. A total of 21 (11%) patients were unwilling to attend the follow-up visit and only returned the questionnaires. A total of 18 (9% of the

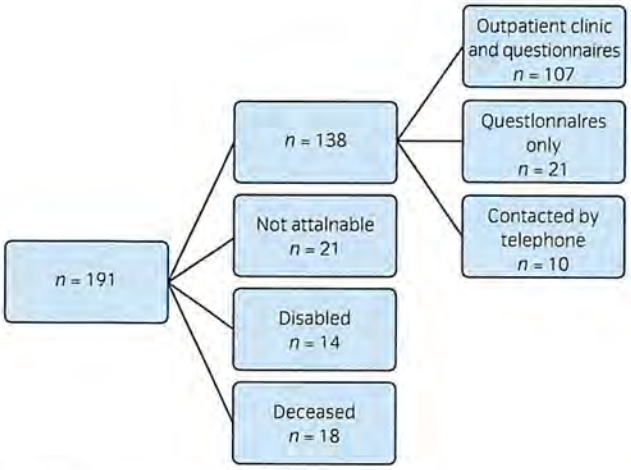

Fig. 1 Study population.

original cohort) patients had died during the follow up of unrelated causes. Of the 35 (21%) patients who did not participate in the evaluation, 21 (11%) were not reached and 14 (7%) were too disabled to attend, mainly because of cognitive disorders. Ten patients could be contacted by telephone.

The mean follow-up time was 126.5 months (range 108–145 months). The mean age at the follow up was 69 years (range 48–93 years). The patient characteristics are presented in Table 1.

Out of 64 patients with MUI preoperatively, 58% (37 patients) and 80% (101 patients out of 127) of SUI patients participated in the present study. By the time of the surgery, the mean age for MUI patients who didn't participate in the present follow-up study was 67 years, whereas the mean age for the whole study group was 60 years.

Of the 128 patients, 100 (78%) had a score of 0–7 in IIQ-7, which is considered as a satisfactory subjective outcome.[11] The results of the questionnaires are presented in Table 2. In all condition-specific questionnaires (UISS, DIS, UDI-6, IIQ-7), all the results were significantly poorer in patients with MUI compared with those with SUI (Table 2). Also, in questionnaires assessing patients' general quality of life and health (EQ-5D and EQ-5D VAS), MUI patients had significantly poorer results. Five patients did not reply to more than two questions in the IIQ-7 or UDI-6 questionnaires, and therefore a total score was not calculated for these patients. Ten out of 37 MUI patients (27%) had persistent urgency at the time of follow up. Six (6.6%) patients developed de novo urgency. The occurrence of urgency was of similar frequency among patients aged over 7 years as among younger patients (34% *vs* 47%, $P = 0.18$).[12]

A total of 18 (14%) patients had a DIS score >7, and at the same time moderate or severe scores at the first and the second questions of the UDI-6 questionnaire indicating urgency or UUI. Patients with chronic illnesses had a poorer health-related quality of life, as assessed with EQ-5D VAS and EQ-5D than healthy patients (65 *vs* 74 and 8.1 *vs* 9.3, respectively, $P < 0.05$ for both). In regard to the patients with recurrent SUI, 12 (31%) out of 39 patients were diagnosed to have MUI preoperatively. There were no statistically significant differences in the results of the questionnaires compared with patients with primary SUI and those with recurrent SUI (Table 3). Of the 10 patients who were contacted by telephone, seven were continent and satisfied with the operation, whereas two of the patients had MUI and one UUI.

Among the 107 patients who were eligible for objective evaluation, a stress test was negative for 100 (93%) patients. The TVT procedure was considered a failure in 11 (10%) patients: six patients had undergone a repeat anti-incontinence procedure and a stress test was positive in six patients, including one reoperated patient with a positive stress test. Repeat anti-incontinence procedures were TVT in one patient and TOT in five patients. One patient of the latter group has had two transobturator procedures; with outside-in and inside-out technique. All these patients are now stress continent, though two of them are using anticholinergic medication for urgency symptoms. These reoperated patients were not included in the analysis. The mean

Table 1 Characteristics of the patients in the original cohort operated on using TVT and in patients evaluated objectively or with the questionnaires after a mean of 10.5 years postoperatively

	Original cohort ($n = 191$)	Evaluated cohort ($n = 128$)†
Median age (years)	60	68
Median BMI	27	26
Estrogen (*n*)‡	119	77
Chronic illnesses (*n*)§	74 (39%)	100 (78%)
• Diabetes	3	10
• Cardiovascular	61	68
• Neurological	4	7
• Respiratory	14	9
Previous gynecological surgery (*n*)	110	
• Incontinence surgery	39	
• Hysterectomy	77	
• Vaginal prolapse surgery	24	
Surgery after the TVT operation (*n*)		
• Incontinence surgery		6
• Bulking agent¶		1
• Hysterectomy		5
• Vaginal prolapse surgery		4

†The 10 patients contacted by telephone are not included in this cohort. ‡Vaginal and/or systemic estrogen. §One patient might have had one or more chronic illnesses. ¶Polyacrylamide hydrogel.

Table 2 Results of the questionnaires at the time of follow up a mean of 10.5 years after the TVT operation

n = 128	SUI† mean ± SD	Range	MUI† mean ± SD	Range	*P*-value‡
IIQ-7 (0–21)	1.8 ± 3.5	0–21	5.7 ± 5.9	0–21	<0.001
UDI-6 (0–18)	3.6 ± 2.9	0–13	7.1 ± 4.9	0–17	<0.001
EQ-5D VAS (0–100)	73 ± 21	10–100	63 ± 19.5	15–100	<0.05
EQ-5D (6–18)	8.3 ± 1.8	6–14	9.1 ± 2.1	6–16	<0.05
VAS (0–100)	22 ± 25.4	0–90	42.7 ± 34	0–100	<0.001
UISS (0–100)	12.9 ± 16.6	0–78	33 ± 25.4	0–90	<0.001
DIS (0–20)	5.3 ± 3.1	0–11	8.9 ± 4.2	0–16	<0.001

†SUI or MUI before the TVT operation. ‡*P*-value representing differences in scores in SUI and MUI patients.

Table 3 Results of the questionnaires evaluating subjective outcome in patients with primary and recurrent SUI after the 10.5 years follow-up

	Primary SUI mean ± SD	Range	Recurrent SUI mean ± SD	Range	*P*-value
IIQ-7 (0–21)	9.9 ± 5	0–28	9.3 ± 3.5	7–20	NS
UDI-6 (0–18)	10.6 ± 4.2	0–23	9.8 ± 3.2	6–19	NS
EQ-5D VAS (0–100)	71.4 ± 19.6	10–100	65.2 ± 65.2	15–100	NS
EQ-5D (6–18)	8.4 ± 1.9	6–16	9.2 ± 2.0	7–14	NS
VAS (0–100)	27.6 ± 29.5	0–95	28.4 ± 28.4	0–100	NS
UISS (0–100)	19.7 ± 22.2	0–90	16.3 ± 19.5	0–70	NS
DIS (0–20)	6.3 ± 3.9	0–16	6.8 ± 3.4	0–13	NS

NS indicates *P*-value >0.05.

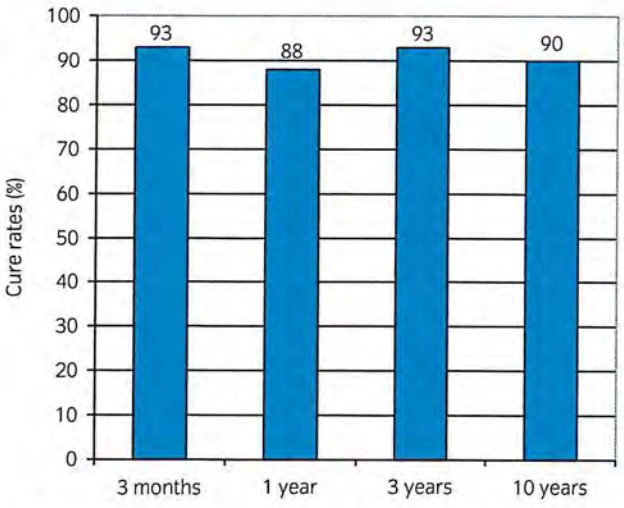

Fig. 2 Objective cure rates after the TVT operation at 3 months, 1 year, 3 years and 10 years follow up. Objective cure rates after 3 months, 1 year and 3 years. Reproduced from Laurikainen *et al.*,[6] with permission. ■, %.

age of the six patients with a positive stress test was 79 years. Two of these patients were primarily operated on because of recurrent SUI. The objective cure rate for the patients with MUI before TVT was 93% (37/40 patients) and with SUI it was 94% (63/67). The overall objective cure rate was 90% of the 107 evaluated patients. The results and cure rates at earlier time-points have been presented in a previous publication (Fig. 2).[6]

In this evaluated cohort, local anesthesia was used in 88% of the patients and spinal anesthesia in 12%. The type of anesthesia did not affect the outcome, nor did any concomitant surgical procedures affect the scores.

The TVT tape was cut below the urethra in two patients; one because of urinary retention at 1 year after the operation and another because of pain at 8 years. The symptoms of both patients disappeared after the re-intervention and the patients remained stress continent. The patient with urinary retention also had urgency incontinence, which was successfully treated with anticholinergic medication and pelvic floor physiotherapy. Recurrent urinary tract infections and pain during urination appeared in one patient 9 years after the TVT procedure. A fiberocystoscopy was carried out by a urologist and a small part of calcificated tape was found to be eroded into the bladder on the right side of the bladder neck. A visible part of the tape was resected at repeat cystoscopies three times. At the latest control more than 11 years after the operation, the patient still had recurrent urinary tract infections and difficulties in emptying the bladder. An abdominal computed tomography and cystos-

copy was scheduled to locate the exact position of the tape. The original TVT operation was carried out uneventfully. A cystoscopy was carried out twice after the insertion of the tape at both sides routinely, as advised in the original TVT technique during the primary operation,[3] and no abnormal findings; for example, perforation or folding of the bladder wall, were discovered. Hospital records of the original cohort did not show any additional complications.

Discussion

The TVT-procedure has become the gold standard of female incontinence surgery. Short-term efficacy and safety have been well demonstrated in numerous studies,[13,14] but there is a paucity of long-term data. In two studies with follow up more than 10 years, objective cure rates were 90% and 84%, respectively.[4,5] Accordingly, in the present study, objective cure of SUI was found to be 90% and subjective cure 78%. The TVT operation is a highly standardized procedure with a routine performance including an intraoperative stress test under local anesthesia, and a cystoscopy after insertion of the tape at each side.[3] When TVT was introduced in Finland, systematic, nationwide, hands-on training for gynecological surgeons was executed.[15] This might contribute to the relatively high cure rates after the long-term follow up.

In the present follow-up study, the outcome could be evaluated objectively in 107 patients and subjectively in 138 patients of the 191 patients who had undergone the TVT procedure a mean of 10.5 years ago. A total of 18 patients had died, and 14 were unable to attend a charge-free follow-up visit to an outpatient clinic. Some patients could not be reached by postal invitation, and some declined participation, partially as they were initially operated on in a hospital different from the follow-up site. The readiness to participate the present study might also have been affected by the relatively high median age of the patients, 68 years. The oldest participant was 93 years. However, the risk of non-responder bias has to be taken into account when interpreting the results of the present study.

There are some studies showing that TVT is also an effective way to treat patients with MUI.[13,16] In contrast, in the present study population,[6] the short-term cure rate of the patients with MUI was significantly lower than of the SUI patients at 36 months of follow up, 69% versus 97%. The same tendency also persisted in the long-term follow up. However, just 58% of the MUI patients participated the present study. The mean age of MUI patients was 7 years higher than that of the SUI patients, which might have affected the readiness of MUI patients to attend. Subjective outcome is likely to be poorer with MUI patients, because of persistent urgency or UUI symptoms. It is obvious, that the stress test is not ideal for testing urgency incontinence symptoms objectively. Omitting preoperative urodynamic testing might be associated with poorer subjective results in MUI patients. The risk of an unsatisfying result is higher with a patient with MUI and should be taken into consideration in connection with the preoperative counselling, as urgency before the operation is predictive of patient satisfaction.[17]

Three years after TVT, the present patient population had a 60% improvement in their urgency symptoms, whereas 4.8% of the patients presented de novo urgency symptoms. After a mean of 10.5 years, de novo urgency was reported by six (6.6%) patients. Previously, de novo urgency or UUI has been reported in 1.5–22% patients after TVT during a follow up from 12 to 36 months.[13,18] De novo urgency is regarded as the most common long-term adverse event after surgical treatment of female SUI. Indeed, it might be even more troublesome for the patient than preoperative SUI.[19] In contrast, after the TVT, urgency symptoms will abate in 54–93% of patients.[5,13] Increasing urgency rates during the follow up might preferentially relate to aging, as the incidence and severity of symptoms of overactive bladder increase progressively with age.[20,21]

The TVT procedure is effective for the treatment of recurrent SUI when the follow-up time has been 20–60 months.[22–24] Rezapour and Ulmsten reported an 82% cure rate and 8% significant improvement of stress urinary incontinence in the study population where some patients have had several operations before the TVT.[25] As repeat surgical intervention, medium cure rates after TOT seem to be lower than after TVT in women with ISD.[22,26] The low pressure urethra and impaired urethral mobility are the risk factors predictive of failure of repeat incontinence surgery.[22,27] Urodynamic examination is required to identify patients with ISD and to guide the surgeon to choose the TVT procedure in these cases. Previous operations might impair urethral function and increase the risk of complications as a result of scarring and altered anatomy. Thus, it is not surprising that the incidence of urgency and UUI are more common after recurrent operations than after the first operation. In the present study, patients operated on with TVT as a repeat procedure had the same long-term outcome than patients with primary SUI.

In the present study, three patients suffered from late tape-related adverse events at 1–11 years postoperatively. In all these cases, the initial TVT procedure and immediate recovery after that proceeded as expected. Two patients with retention and pain had the tape cut without any further problems. One patient had recurrent urinary tract infections and dysuria as a result of tape erosion into the bladder and had to undergo at least three cystoscopies to remove the visible tape from the bladder wall. Irritating symptoms, recurrent urinary tract infections and pain during urination might emerge several years after the primary operation, and need to be taken into consideration as a sign of late complication of TVT. Tape erosion might develop because of possible submucosal placement of the tape or pressure necrosis

of the bladder wall.[28,29] In patients with prolonged or later-appearing urinary symptoms, a cystoscopy should be carried out, even many years afterwards.

The results of the present long-term follow-up study of patients with primary or recurrent SUI and concomitant procedures undergoing TVT operation are encouraging. The TVT shows excellent durable subjective and objective cure rates in SUI patients, and shows similar durable objective efficacy for SUI component of MUI patients. However, a long-term subjective cure might not be achieved by this procedure in MUI patients, even when they predominantly complain of SUI. The long-term complications of the TVT are very few.

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Conflict of interest

None declared.

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Appendix 1. Urinary Incontinence Severity Score (UISS)

1.	Do you experience urine leakage not related to effort or position (for example lying down)?	Not at all	Sometimes	Often
2.	Do you experience urine leakage to minor physical activity (e.g. walking or rising)?	Not at all	Sometimes	Often
3.	Do you experience urine leakage related to sudden, strong physical activity or even coughing or sneezing?	Not at all	Sometimes	Often
4.	Has urine leakage disturbed your daily chores (shopping, cooking, housecleaning etc.)?	Not at all	Sometimes	Often
5.	Has urine leakage disturbed your employment (client service, work performance etc.)?	Not at all	Sometimes	Often
6.	Are you afraid that others will notice your problem (fear of your odour or wetness etc.)?	Not at all	Sometimes	Often
7.	Do you have to restrict or give up social activities (such as visiting friends, physical activity, theatre, church etc.)?	Not at all	Sometimes	Often
8.	Do your incontinence symptoms disturb your sex life?	Not at all	Sometimes	Often
9.	Does incontinence cause irritation of your external genital organs?	Not at all	Sometimes	Often
10.	How often must you use a protective happy or pad?	Not at all	Sometimes	Often

Appendix 2. Detrusor Instability Score (DIS)

Please circle the most suitable response to the questions below.

		0	1	2
1.	How many times per day do you urinate?	5–7	8–10	Over 10
2.	How many times at night do you have to get up to urinate?	0–1	2–3	Over 3
3.	Do you feel there is still urine in the bladder after urinating?	No	Sometimes	Often
4.	Does hurry and tension cause urge to urinate?	No	Slightly	Strongly
5.	Do you have urinary leakage during stress (coughing, sneezing, laughing)?	Yes		On other occasions as well
6.	Does the leakage of urine happen immediately in connection with stress?	Immediately		After some time
7.	Do you feel need to urinate before the leakage of urine?	No	Slightly	Strongly
8.	Have you had treated urinary infections during the past two years?	No	1–2	More than 2/chronically
9.	How much is the amount of urinary leakage at a time?	Drops	A certain amount	Bladder empties completely
10.	Can you stop the stream of urine while urinating?	Yes	Fairly well	No

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Platinum Priority – Incontinence
Editorial by XXX on pp. x–y of this issue

Five-year Results of a Randomized Trial Comparing Retropubic and Transobturator Midurethral Slings for Stress Incontinence

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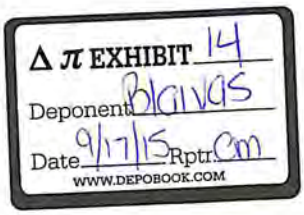
Abstract

Background: Midurethral slings have become the most preferred surgical treatment for female urinary incontinence.
Objective: To compare the efficacy and safety of two midurethral sling procedures with a different technique of sling insertion 5 yr after intervention.
Design, setting, and participants: Multicenter randomized clinical trial conducted in seven public hospitals in Finland including primary cases of stress urinary incontinence.
Intervention: Surgical treatment with the retropubic tension-free vaginal tape (TVT) procedure or the transobturator tension-free vaginal tape (TVT-O) procedure.
Outcome measurements and statistical analysis: Objective treatment success criteria were a negative stress test, a negative 24-h pad test, and no retreatment for stress incontinence. Patient satisfaction was assessed by condition-specific quality-of-life questionnaires.
Results and limitations: A total of 95% of the included women could be assessed according to the protocol 5 yr after surgery. The objective cure rate was 84.7% in the TVT group and 86.2% in the TVT-O group, with no statistical difference between the groups. Subjective treatment satisfaction was 94.2% in the TVT group and 91.7% in the TVT-O group, with no difference between groups. Complication rates were low, with no difference between groups.
Conclusions: Both objective and subjective cure rates were >80% in both groups even when women lost to follow-up were included as failures. The complication rates were low, with no difference between the groups. No late-onset adverse effects of the tape material were seen.
Patient summary: Female urinary stress incontinence can be treated surgically with minimally invasive midurethral sling procedures. Two main approaches of sling placement have been developed: the retropubic and the transobturatory. We compared both approaches and followed the patients for 5 yr. We found no difference in cure rate between the procedures, and patient satisfaction was high.
Trial registration: ClinicalTrials.gov identifier NCT00379314.



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1. Introduction

Urinary incontinence affects an increasing number of aging women worldwide. As many as 20–50% experience urinary incontinence [1,2], a substantial part of which is stress or mixed incontinence, with the potential to be cured by incontinence surgery.

Proof of the efficacy of the midurethral concept [3] of supporting the urethra for treatment of female urinary stress incontinence was presented by Ulmsten et al. in 1996 [4], and it has profoundly changed the surgical practice of treating female stress or mixed urinary incontinence. The tension-free vaginal tape (TVT) procedure, designed to be performed under local anesthesia as day surgery, has become the gold standard of incontinence surgery because of its efficacy, safety, and longevity [5]. A rapid spread of use of the TVT operation throughout the world revealed risks of complications not experienced within the initial trials with a follow-up ≥3 yr [6]. Complications such as bladder and bowel perforations led to a modification of the TVT procedure by passing the tape material through the obturator foramen [7,8]. Short-term observational and randomized trials suggest that the transobturator procedure is as effective as the initial retropubic approach [9,10]. Conflicting data exist on the overall risk of complications associated with the two procedures, however. The nature of the complications reported differs between the procedures [11].

In 2004, we initiated a randomized trial comparing the original retropubic TVT operation with the so-called inside-out transobturator operation, the TVT-O procedure, with the aim of finding differences in cure rates and complication rates between the two procedures during long-term follow-up. The immediate postoperative [12], 12-mo [10], and 36-mo [13] follow-up reports of this trial have been published. We report the 5-yr results of this randomized trial.

2. Methods

2.1. Study design

This was a multicenter randomized trial including seven centers in Finland (four university and three central hospitals) comparing the TVT with the TVT-O procedure for the treatment of stress urinary incontinence. Recruitment was performed among women admitted to the hospitals for treatment of stress urinary incontinence. Women were eligible if they had a history of stress urinary incontinence and an indication for surgical treatment of their incontinence, a positive cough stress test performed in a semi-lithotomy sitting position with a comfortably filled bladder (estimated to 200–300 ml), and a Detrusor Instability (overactivity according to the latest International Continence Society terminology) Score (DIS) of ≤7. DIS is a validated 10-item questionnaire, with a score of 0–20, to distinguish between stress and urgency incontinence. A score ≤7 is representative for stress incontinence [14]. Exclusion criteria are presented in Table 1 including urogenital prolapse more then second grade according to Baden-Walker [15].

The women were randomized into groups using a computer-generated random allocation in a 1:1 ratio in balanced blocks of four. The investigators called an independent randomization center after obtaining written informed consent from the women. The 5-yr follow-up assessment was performed by an independent physician or occasionally by the surgeon together with an independent research nurse. The trial was approved by the Helsinki University Central Hospital ethics committee.

Table 1 – Exclusion criteria

Previous incontinence surgery
Postvoid residual urine volume >100 ml
Urogenital prolapse more than second degree
Body mass index >35 kg/m^2
Active malignancy or previous radiation therapy of the pelvis region
Anticoagulant therapy or hemophilia
Neurogenic disease associated with bladder disorders
Current or more than three urinary tract infections within the past year
Anticholinergic or duloxetine medication

2.2. Study procedures

The midurethral slings used were the TVT and the TVT-O slings (Gynecare, Ethicon, Johnson & Johnson, Somerville, NJ, USA), both introducing the tape starting at the vaginal incision and both using the same macroporous monofilament type 1 polypropylene tape. The operations were performed as originally described by Ulmsten et al. [4] and De Leval [8], respectively. All procedures were performed under local analgesia with light sedation, to keep the patients cooperative. A cough stress test was performed intraoperatively to avoid postoperative voiding difficulties. The tapes were adjusted during vigorous coughs with a bladder filled with 300 ml of saline. At the final adjustment a drop of saline was allowed to escape. Cystoscopy with a 70° optic lens was performed intraoperatively in all cases. No concomitant surgery was performed. The surgeries in all seven participating public hospitals were performed according to the routines of the hospitals. The manufacturer of the slings did not provide any material for the trial and had no part in the planning of the trial, the analysis of the data, or the preparation of the manuscript. The trial was initiated by the responsible researchers and funded solely by governmental research grants.

2.3. Outcomes

The primary outcome was objective and subjective treatment success. Objective success criteria were a negative cough stress test performed in the same manner as required for inclusion into the trial, a negative 24-h pad test (<8 g per 24 h), and no retreatment for stress incontinence. Subjective success or patient satisfaction was assessed by asking if the operation had met their expectations completely, partly, or not at all. Significant improvement in the following condition-specific quality-of-life (QoL) questionnaires: the Urinary Distress Inventory (6 items) (UDI-6) [16], the Incontinence Impact Questionnaire (7 items) [16], the Urinary Incontinence Severity Score [17], and a Visual Analog Scale (VAS) [17], in which 0 represents no urinary problems and 100 unbearable urinary problems, were additionally used as criteria of subjective treatment success.

Complications such as de novo urgency incontinence and/or symptoms, self-reported voiding difficulties, urinary tract infections (UTIs), and tape extrusion or erosion were registered. De novo urgency incontinence was defined as a DIS score >7 and moderate or severe symptoms of urgency associated with urinary leakage in the UDI-6; de novo urgency symptoms were defined as new symptoms of frequency of moderate or severe degree in the UDI-6 and a DIS score >7. Objective signs of voiding difficulties were estimated by postvoid residual (PVR) volumes >100 ml and UTIs by a history of infections treated by antibiotics during the past 2 yr. Tape extrusion or erosion was explored thorough clinical examination including speculum examination in a lithotomy position and careful palpation.

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Statistical analysis was performed using SPSS software for Windows v.15.0 (IBM Corp, Armonk, NY, USA). Continuous variables were analyzed with the paired-sample *t* test and the independent-sample *t* test to calculate statistical differences between and within the study groups. The chi-square test was applied for categorical values. A *p* value <0.05 was considered to indicate statistical significance. Sample size calculation was performed assuming a 95% success rate for the TVT procedure and assuming a 10% difference in either success rate or rates of complications would be clinically important. With a 70% power to show a 10% difference, the sample size should be 260 patients with 130 in each group.

3. Results

Between March 2004 and November 2005, 273 women were randomly assigned to either the TVT or the TVT-O procedure. A total of 268 women of the randomized 273 women underwent the allocated operation: 136 TVT operations and 132 TVT-O operations. Four women refused the operation after randomization, and one woman could not participate because she was undergoing surgery unrelated to urogynecologic problems. Figure 1 shows a flowchart of the trial. The baseline demographics were similar between the groups (Table 2).

Overall, 254 women returned to the clinics for their 5-yr follow-up visit. Thus 94.8% of the women (254 of 268) could be assessed per protocol. Fourteen women were not available for assessment: 5 in the TVT group (5 of 136) and 9 in the TVT-O group (9 of 132). One woman had died, two women had moved abroad, six women refused to return to the clinic, and five women had undergone a repeat incontinence operation.

Among the 254 women assessed according to the protocol, 84.7% (111 of 131) in the TVT group had a negative stress test, a negative pad test, and had had no retreatment

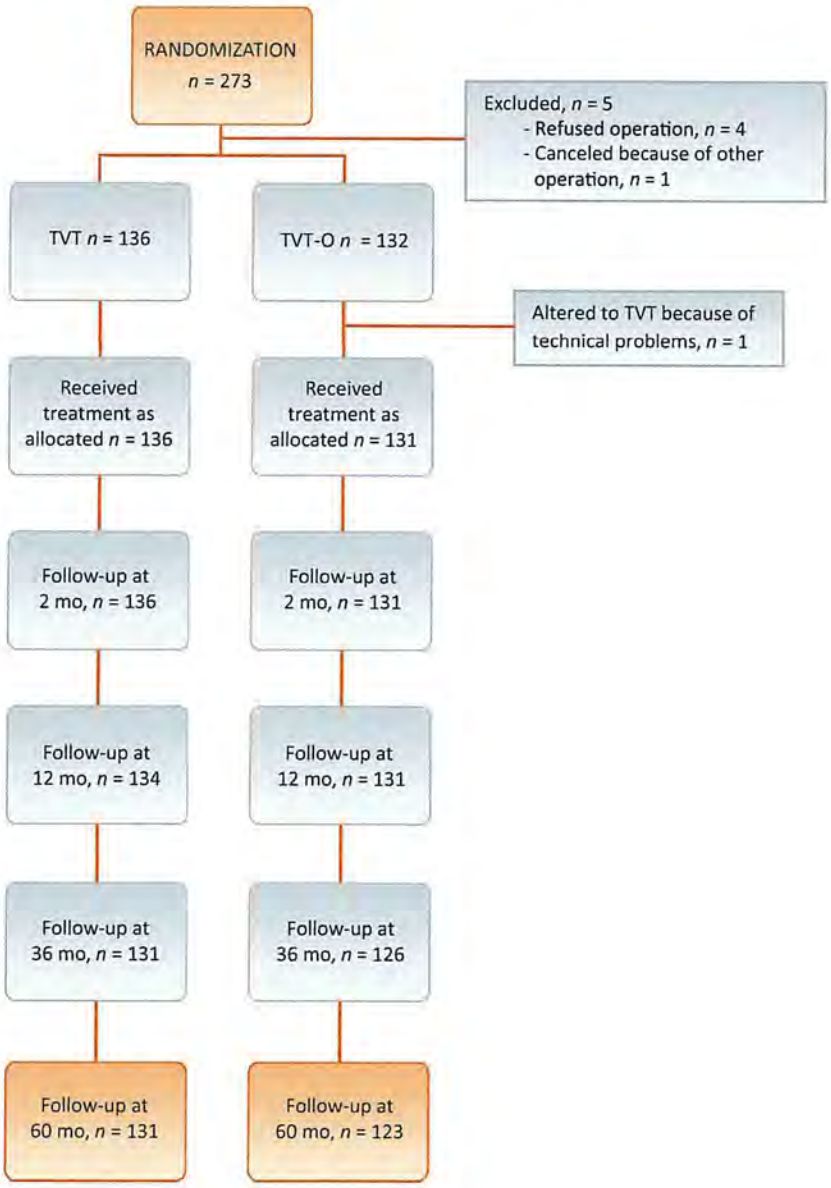

Fig. 1 – Flowchart of the study.
TVT = tension-free vaginal tape; TVT-O = transobturator tension-free vaginal tape.

Table 2 – Patient demographics

	TVT	TVT-O
Age, yr, mean ± SD	53 ± 10	54 ± 10
Parity, median (range)	2 (0–6)	2 (0–7)
Postmenopausal, *n* (%)	71 (52)	78 (60)
HRT, *n* (%) of postmenopausal women	50 (37)	50 (38)
BMI, mean ± SD	26 ± 3	26 ± 4
Hysterectomized, *n* (%)	35 (26)	41 (31)
Previous gynecologic laparotomies, *n* (%)	37 (27)	35 (27)
Previous surgery for prolapse, *n* (%)	7 (5)	12 (9)
Duration of symptoms, yr ± SD	7 ± 6	10 ± 7*
Pad test, g, mean ± SD	44 ± 39	44 ± 48

BMI = body mass index; HRT = hormone replacement therapy; SD = standard deviation; TVT = tension-free vaginal tape; TVT-O = transobturator tension-free vaginal tape.
* $p = 0.0025$.

Table 4 – Preoperative and 5-yr follow-up results of condition-specific quality-of-life questionnaires

	TVT		TVT-O	
	Preoperative (*n* = 136)	5 yr (*n* = 131)	Preoperative (*n* = 132)	5 yr (*n* = 123)
UISS	11 ± 3	1 ± 3*	11 ± 3	1 ± 2*
DIS	4 ± 2	3 ± 3*	4 ± 2	3 ± 3*
VAS	65 ± 20	11 ± 21*	67 ± 21	9 ± 17*
IIQ-7	16 ± 4	8 ± 2*	16 ± 4	8 ± 2*
UDI-6	14 ± 3	8 ± 2*	13 ± 3	8 ± 2*

DIS = Detrusor Instability Score; IIQ-7 = Incontinence Impact Questionnaire (7 items); TVT = tension-free vaginal tape; TVT-O = transobturator tension-free vaginal tape; UDI-6 = Urogenital Distress Inventory (6 items); UISS = Urinary Incontinence Severity Score; VAS = Visual Analog Scale.
Data are expressed as mean plus or minus standard deviation.
* $p < 0.0003$; significant difference compared with preoperative figures.

because of stress incontinence. The corresponding figures for the women in the TVT-O group were 86.2% (106 of 123), respectively; the differences between the groups were not statistically significant. The objective success rate considering all women lost to follow-up as failures were 81.6% (111 of 136) in the TVT group and 80.3% (106 of 132) in the TVT-O group.

Subjective success, expressed as treatment completely meeting expectations, was experienced by 84.6% (115 of 136) in the TVT group and 85.6% (113 of 132) in the TVT-O group. Including even those who thought that expectations had partly been met, the corresponding subjective improvement rates were 94.2% in the TVT group and 91.7% in the TVT-O group (Table 3). A significant improvement from preoperative scores was seen in all condition-specific QoL questionnaires for both groups, with no difference between the groups (Table 4).

De novo urgency incontinence was experienced by 2.8% of the women (7 of 254) at their 5-yr follow-up visit, 3.1% (4 of 131) in the TVT group and 2.4% (3 of 123) in the TVT-O group. Of these seven women, five were using anticholinergic medication, none had a PVR >100 ml, and four women had experienced one or more UTIs (range: 1–9) during the past 2 yr. None of these seven women fulfilled the criteria of urgency incontinence at their 2-mo follow-up visit; one and three women did at the 12-mo and 36-mo visit, respectively. De novo urgency symptoms were recorded in only five women, three of these having de novo urgency incontinence. Frequency and urgency symptoms of moderate or severe degree in the UDI-6 were experienced preoperatively by 28.0% (75 of 268) of the women; only 4.7% (12 of 254) experienced these symptoms at their 5-yr follow-up. Thus 84% of the women were cured of their preoperative urgency symptoms.

At least one episode of UTI (range: 1–9) had required treatment with antibiotics in 21.3% (54 of 254) of the women, 20.6% in the TVT and 22.1% in the TVT-O group. Sixteen women (6.3%) had had between three and nine UTIs during the last 2 yr. The mean amount of PVR among these 16 women was ±23.0 ml. Six women (4.6%) in the TVT group and 7 women (5.7%) in the TVT-O group had a PVR >100 ml, mean ±144 ml (range: 107–180) and ±195 ml (range: 125–360), respectively. The mean plus or minus standard deviation amount of PVR was ±24.9 ml in the total population; the mean amount in those who had not experienced a UTI during the last 2 yr was ±26.3 ml (199 of 254). Among those who had had one or more UTI, the PVR was ±19.8 ml (54 of 253).

No woman had any sign of tissue reaction, erosion, or tape protrusion at their 5-yr follow-up. During the course of the study, two women experienced tape problems, both in the TVT-O group. One woman had a tape extrusion 1 yr postoperatively. The midline visible part of the tape was excised, resulting in incontinence, and she later had a TVT operation. One woman had retention problems, and the tape was cut in the midline twice, which resolved the retention, but she experienced urgency symptoms.

Table 3 – Patient satisfaction with the tension-free vaginal tape and the transobturator tension-free vaginal tape operations 5 yr postoperatively

	TVT		TVT-O		
Expectations met:					
Completely	84.6%	115/136	85.6%	113/132	NS
Partly	9.6%	13/136	6.1%	8/132	NS
Not at all	2.2%	3/136	0.8%	1/132	NS
Lost to follow-up	3.7%	5/136	6.8%	9/132	NS
Recommend to a friend:					
Yes	92.6%	126/136	88.6%	117/132	NS
Probably	2.9%	4/136	2.3%	3/132	NS
No	0.7%	1/136	1.5%	2/132	NS
Lost to follow-up	3.7%	5/136	6.8%	9/132	NS

TVT = tension-free vaginal tape; TVT-O = transobturator tension-free vaginal tape.

4. Discussion

The present long-term follow-up results of our randomized multicenter trial show no difference in objective and subjective success rates between the retropubic and the transobturator approach of placing a midurethral tape for the treatment of female stress urinary incontinence. The strength of this trial is that we were able to asses 95% of the initially enrolled women according to the protocol 5 yr after